

APPENDIX 6

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

RHÔNE-POULENC AGRO S.A.,
(Now known as Aventis CropScience SA)
Plaintiff,
v.

C.A. NO. 1:97cv1138

MONSANTO COMPANY
(Now known as Pharmacia Corporation)

and

DEKALB GENETICS CORPORATION,
Defendants.

**RPA'S POST-TRIAL BRIEF OF
FINDINGS OF FACT
AND
CONCLUSIONS OF LAW**

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I. INTRODUCTION

A. History of the Case

The present proceeding arises under the patent laws of the United States, specifically, 35 U.S.C. § 256, which authorizes courts to correct the names of inventors on issued U.S. patents.

Rhône-Poulenc Agro S.A., now known as Aventis CropScience S.A. ("RPA"), is a French corporation, whose U.S. headquarters are located at Research Triangle Park, North Carolina. DeKalb Genetics Corporation ("DeKalb") is a wholly owned subsidiary of Pharmacia Corporation, previously and also known as Monsanto Company ("Monsanto").

The prior history of this case is set forth in the Court's Memorandum Opinion of February 8, 2000 (Doc. # 538) ("February 8 Opinion"), and will not be repeated here. Briefly, RPA filed suit on October 30, 1997, against DeKalb and Monsanto seeking, *inter alia*, a rescission of a 1994 Agreement between RPA, DeKalb, and Calgene, Inc. ("Calgene"), based on breach of contract and fraud in the inducement, as well as seeking damages, accounting, and other equitable relief. Predicated on the rescission of the 1994 Agreement, RPA also sued defendants for infringement of RPA's U.S. patent 5,510,471, now Patent RE 36,449 ("471 patent"), and for trade secret misappropriation. The outcomes of the two trials on these issues are detailed in the February 8 Opinion.

In 1999, RPA amended its pleadings to assert the present joint-inventorship claims (Doc. # 278), which were further amended in April 2000 (Doc. # 557). The DeKalb patents to which RPA asserted joint inventorship were: U.S. Patents 6,040,497 ("497 patent" or "Spencer patent"); 5,554,798 ("798 patent" or "Lundquist patent"); 6,025,545; and 5,990,390. Shortly before trial, the parties advised the Court that they had resolved the issues as to U.S. Patents 6,025,545 and

5,990,390, and the action as to those patents was dismissed (Docs. #627 & #628). Trial was had as to the 497 and 798 patents. To expedite trial, RPA directed its evidence to only claim 46 of the Spencer 497 patent and claim 1 of the Lundquist 798 patent. RPA had asked for a jury trial of the claims, to which DeKalb objected on grounds that there was no right to a jury trial for inventorship issues. The Court, in response, and without objection by DeKalb or RPA, empaneled an advisory jury, while reserving final determination for the Court. Trial was held over nine days from August 22 to September 1, 2000.

B. Advisory Jury Verdict

The Verdict Form with the jury's responses are set forth in full below:

VERDICT FORM

Questions Directed to the Spencer 497 Patent

- A. Has RPA proven by clear and convincing evidence that the named inventors of the Spencer 497 patent did not alone conceive the entire scope of the subject matter of claim 46?

YES ✓ NO

If the answer to this question is "Yes" please go to and consider the next question. If the answer is "No", please go to Question B.

- A1. Has RPA proven by clear and convincing evidence that one or more of its scientists contributed to the conception of claim 46 of the Spencer 497 patent?

YES ✓ NO

If the answer to the above question is "Yes", please place a check mark by the name of the scientist or scientists who made such a contribution, then go to and consider question A2. If "No", please go to and consider Question B.

Rick DeRose ✓
Georges Freyssinet ✓

Michel Lebrun ☒
 Bernard Leroux ☒
 Alain Sailland ☒

- A2. Has RPA proven by clear and convincing evidence that one or more of RPA's scientists contributed to the conception of claim 46 by providing to DeKalb the DNA constructs included in transformation events GG25, GA21, GJ11 and FI117 of claim 46?

YES ☒ NO ☐

If the answer to the above question is "YES", please place a check mark by the name of the scientist or scientists who contributed to the DNA constructs.

Rick DeRose ☒
 Georges Freyssinet ☒
 Michel Lebrun ☒
 Bernard Leroux ☒
 Alain Sailland ☒

- A3 Has RPA proven by clear and convincing evidence that transformation events GG25, GA21, GJ11, AND FI117 were products of a collaboration between one or more of RPA and DeKalb scientists?

YES ☒ NO ☐

- A4a. Has RPA proven by clear and convincing evidence that the scientist or scientists beside whose name you have placed a check mark in response to Question A1 did more than contribute well known principles or disclose what was shown in publicly available scientific literature or describe what was then available in the marketplace or explain how the material in the public domain works or did more than explain to the DeKalb scientists concepts that are well-known and the current state of the art?

YES ☒ NO ☐

If the answer to the above question is "Yes", please place a check mark by the name of the scientist or scientists who made such a contribution.

Rick DeRose ☒
 Georges Freyssinet ☒
 Michel Lebrun ☒

Bernard Leroux ☒ ☐
Alain Sailland ☒ ☐

- A4b. Has RPA proven by clear and convincing evidence that the scientist or scientists beside whose name you have placed a check mark in response to Question A1 made a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention?

YES ☒ ☐ NO ☐ ☐

If the answer to the above question is "YES", please place a check mark by the name of the scientist or scientists who made such a contribution.

Rick DeRose ☒ ☐
Georges Freyssinet ☒ ☐
Michel Lebrun ☒ ☐
Bernard Leroux ☒ ☐
Alain Sailland ☒ ☐

Questions Directed to the Lundquist 798 Patent

- B. Has RPA proven by clear and convincing evidence that the named inventors of the Lundquist 798 patent did not alone conceive the entire scope of the subject matter of claim 1?

YES ☒ ☐ NO ☐ ☐

If the answer to this question is "Yes" please go to and consider the next question. If the answer is "No", please have the foreperson sign and date the signature page of this verdict form and return to the courtroom.

- B1. Has RPA proven by clear and convincing evidence that one or more of its scientists contributed to the conception of claim 1 of the Lundquist 798 patent?

YES ☒ ☐ NO ☐ ☐

If the answer to the above question is "Yes", please place a check mark by the name of the scientist or scientists who made such a contribution then go to and consider question B2. If "No", please have the foreperson sign and date the signature page of the verdict form and return to the courtroom.

Rick DeRose ☒ ☐

Georges Freyssinet ☒ ☐
Michel Lebrun ☒ ☐
Bernard Leroux ☒ ☐
Alain Sailland ☒ ☐

B2. Has RPA proven by clear and convincing evidence that RPA's scientists contributed to the conception of claim 1 by:

- a) contributing to the conception of fertile transgenic corn containing DNA constructs encoding non-bacterial mutated plant EPSP synthases?

YES ☒ ☐ NO ☐ ☐

If the answer to the above question is "Yes", please place a check mark by the name of the scientist or scientists who made such a contribution.

Rick DeRose ☒ ☐
Georges Freyssinet ☒ ☐
Michel Lebrun ☒ ☐
Bernard Leroux ☒ ☐
Alain Sailland ☒ ☐

- b) contributing to the conception of fertile transgenic corn containing DNA constructs encoding EPSP synthases that provide glyphosate resistance to corn?

YES ☒ ☐ NO ☐ ☐

If the answer to the above question is "Yes", please place a check mark by the name of the scientist or scientists who made such a contribution.

Rick DeRose ☒ ☐
Georges Freyssinet ☒ ☐
Michel Lebrun ☒ ☐
Bernard Leroux ☒ ☐
Alain Sailland ☒ ☐

B3. Has RPA proven by clear and convincing evidence that claim 1 was the product of a collaboration between RPA and DeKalb scientists or work under common direction?

YES ☒ ☐ NO ☐ ☐

If your answer is "Yes", please place a check mark by the name of the scientist or scientists who participated in the collaboration or joint effort either with DeKalb scientists or other RPA scientists who were participating in the joint effort with DeKalb scientists.

Rick DeRose ☒ ☐
Georges Freyssinet ☒ ☐
Michel Lebrun ☒ ☐
Bernard Leroux ☒ ☐
Alain Sailland ☒ ☐

- B4a. Has RPA proven by clear and convincing evidence that the scientist or scientists beside whose name you have placed a check mark in response to Question B1 did more than contribute well known principles or disclose what was shown in publicly available scientific literature or describe what was then available in the marketplace or explain how the material in the public domain works or did more than explain to the DeKalb scientists concepts that are well-known and the current state of the art?

YES ☒ ☐ NO ☐ ☐

If the answer to the above question is "Yes", please place a check mark by the name of the scientist or scientists who made such a contribution.

Rick DeRose ☒ ☐
Georges Freyssinet ☒ ☐
Michel Lebrun ☒ ☐
Bernard Leroux ☒ ☐
Alain Sailland ☒ ☐

- B4b. Has RPA proven by clear and convincing evidence that the scientist or scientists beside whose name you have placed a check mark in response to Question B1 made a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention?

YES ☒ ☐ NO ☐ ☐

If the answer to the above question is "Yes", please place a check mark by the name of the scientist or scientists who made such a contribution.

Rick DeRose ☒ ☐
Georges Freyssinet ☒ ☐

Michel Lebrun ✓
Bernard Leroux ✓
Alain Sailland ✓

C. Effect of Advisory Jury Verdict

The function of the advisory jury is only to enlighten the trial court. An advisory jury does not replace the court as trier of fact in the case. The responsibility for rendering a decision as the trier of fact remains with the judge, even though an advisory jury is used. The verdict of the advisory jury has no binding effect on the court. The court may accept the advisory verdict and make findings in accordance with it; or the court may reject the advisory verdict in whole or in part. Vol. [8] James Wm. Moore et al., Moore's Federal Practice, § 39.42[1] and [2] (1999).

II. FACTUAL OVERVIEW

A. Glyphosate Resistant Corn

Scientists have been working to create genetically modified crops having beneficial traits for many years. Engineering plants to resist glyphosate herbicides has been a particularly coveted goal, due to the popularity of glyphosate as a systemic, non-selective post-emergent herbicide that is environmentally friendly and safe. Although progress had been made in engineering other crops and plants, by 1990 glyphosate resistant corn still had not been attained. Making glyphosate resistant corn required both (1) genetic materials that would stably integrate into corn cells and express in the corn cells to provide the requisite resistance, and (2) a means for transforming and regenerating corn cells with the genetic materials in such a way that the genetic materials would be inherited in subsequent progeny.

B. RPA's Relationship With Calgene

A significant amount of trial was devoted to RPA's relationship with Calgene, in view of DeKalb's contention that RPA's "EPSPS" and "OTP" contributions originated from Calgene. RPA, therefore, here addresses the history and substance of the relationship between Calgene and RPA relating to those issues.

Around 1985, RPA began a collaboration with Calgene to develop Calgene's bacterial *aroA* EPSPS gene for glyphosate resistance, which was called the CT7 gene. CT7 had been developed by Calgene's Dr. Luca Comai by random mutagenesis of *Salmonella Typhimurium* bacteria. (DeRose Tr. 137-39). Dr. Comai had already published various articles disclosing the CT7 *aroA* gene, including the DNA sequence and disclosing that the mutated EPSPS enzyme had a Proline to Serine mutation at the so-called "101" position. (Freyssinet Tr. 589; Comai Tr. 854-57; PTX-1445; DTX-129, 148). Calgene also sought and obtained patents covering the invention. (Comai Tr. 856-57; DTX-131, 160).

In 1985-86, RPA and Calgene negotiated and entered into a "Partnership Agreement" by which RPA would fund research and development of that bacterial EPSPS invention at Calgene. (Freyssinet Tr. 589-90). Calgene provided the *aroA* gene and its experience, while the funding was RPA's sole required contribution to the "partnership," or as Dr. Comai stated:

Q. Who paid for the work? That is, who funded the work to create this DNA with B808 and CT7, or 97 and 101 mutations?

A. Well, it was a participation of the companies. There was -- when the companies got together, there was the putting of all resources in the project, and Calgene was putting in years of work on this system with large expenses and Rhone-Poulenc put in cash, because they were not coming in with any assets but cash.

(Comai Tr. 886). The scientific work of the partnership was directed by a Scientific Committee, which included two members from each of Calgene and RPA. Dr. Georges Freyssinet of RPA and Dr. Luca Comai of Calgene were two members of that Committee. (Freyssinet Tr. 590-91).

Calgene provided the CT7 gene to RPA, with which RPA began working in its own laboratories to see if RPA could increase its effectiveness. (Freyssinet Tr. 592-93). Calgene continued its efforts. (*Id.*). The continuing experiments, however, were not demonstrating that CT7 would provide requisite glyphosate resistance in plants. (Freyssinet Tr. 593). Therefore, the RPA-Calgene Scientific Committee determined that Calgene should perform routine lab-technician experiments to identify randomly mutagenized bacterial *aroA* genes that showed resistance to glyphosate in bacteria, in a fashion similar to that which uncovered CT7. (Freyssinet Tr. 593-96). That effort identified the so-called B808 *aroA* gene that encoded an EPSPS enzyme having three mutations, one of which was a Threonine to Isoleucine mutation at the so-called "97" position (Freyssinet Tr. 596, 597-98; Comai Tr. 859). Although DeKalb portrays B808 as a "Calgene" invention, B808 was isolated by lab technician experimentation requisitioned by the RPA-Calgene Scientific Committee that included Dr. Freyssinet. (Freyssinet Tr. 593).¹

¹ The process for making B808 was as follows: A chemical known to mutate bacterial DNA, ethyl methanesulfonate or EMS, is applied to a petri dish of bacteria which is then propagated. The EMS causes random mutations in the DNA of the bacteria of various genes, including *AroA*. Thereafter, increasing amounts of glyphosate are added to the bacterial cultures to determine if any bacteria survive. Any bacteria growing in the culture necessarily had its *AroA* DNA changed to tolerate glyphosate. That mutated *AroA* gene is then isolated. The system permits testing of literally millions of random mutations of the bacterial *AroA* gene. Any modified gene isolated from the tests would then have to be incorporated into DNA constructs and tested, in the same fashion as was the CT7 gene. (Freyssinet Tr. 594-96; Comai Tr. 858-59).

Initial enzymatic experiments suggested that "B808 in vitro was at least five times more resistant to glyphosate than the CT7." (Freyssinet Tr. 598-99). Both RPA and Calgene incorporated B808 into their respective DNA constructs and began evaluating the gene. (Freyssinet Tr. 599).

In April 1989, Dr. Comai proposed to the Scientific Committee a series of various new random and site-directed mutagenesis experiments with the bacterial *aroA* genes, including one to combine CT7 into the B808 gene. (Freyssinet Tr. 599-602, 753; PTX-1429 [last page]). That experiment would have resulted in an *aroA* gene with four sets of mutations — the three mutations existing in the B808 combined with the "101" mutation of CT7. (Freyssinet Tr. 601-02, 609, 753). The RPA-Calgene Scientific Committee rejected that in favor of having Calgene make *aroA* genes having only the "97" mutation, and another combining the "97" and "101" mutations. (Freyssinet Tr. 609-12; PTX-1429 [at 031675]).

Calgene made the "97" mutation gene, which it called CT9. (Freyssinet Tr. 612-13). Dr. Comai also began the process of combining the "97" and "101" mutations in a gene. (DTX-1497). Before that combined "97" plus "101" bacterial gene was actually made, however, it was discovered that B808 gene failed to impart more glyphosate resistance to plants than CT7, and, more importantly, Calgene itself demonstrated that the *aroA* EPSPS genes with the so-called "97" mutation were toxic — i.e., the bacteria having that *AroA* mutation dies, presumably because the EPSPS enzyme did not normally function in the bacterial biosynthesis pathway. (Freyssinet Tr. 615-19, 621-22; PTX-1431 [at CAL004229]). The minutes of the October 1989 RPA-Calgene Scientific Committee state:

All showed some toxicity but B808 clearly the worst, CT9 (97 thr-> isoleu by site-directed mutagenesis) confirmed B808 toxicity. Toxicity to E.Coli is triggered by 97 thr ->isoleu mutation.

(PTX- 1431 [at CAL004229]). Calgene itself decided to drop further development of that "97" mutation in view of the toxicity, and never further pursued or suggested pursuing genes containing the "97" mutation, and no further mention was made of the "double mutation" of "97" plus "101." (Freyssinet Tr. 619-20; PTX-1431).

Shortly thereafter, both Calgene and RPA determined that development of the Calgene *aroA* genes was at "Case 1" — i.e., that no progress had been made from the beginning of the effort. (Freyssinet Tr. 622-24; PTX-1432 [¶ 2]). Also by the end of 1989, Dr. Comai left Calgene, and Calgene was not willing to invest any more effort into glyphosate resistance, unless RPA would fund all the work. (Freyssinet Tr. 623-25; Comai Tr. 858; PTX-1432). RPA decided to not fund Calgene's effort further. (Freyssinet Tr. 625). Actual technical collaboration between RPA and Calgene on glyphosate resistance ended by the end of 1989. (*Id.*; Comai Tr. 857-58).

RPA and Calgene did not work together on the other elements of RPA's DNA constructs — particularly the OTP and the promoters — which were developed by RPA entirely independently of Calgene and Dr. Comai. (Freyssinet Tr. 750).

C. Results of Work with Calgene's Bacterial *aroA* Genes

Calgene's CT7 and B808 *aroA* genes were tested for glyphosate resistance by Calgene, RPA, DeKalb and others, by transforming various crops, including tobacco, carrots, canola, and corn, with various DNA constructs comprising those *aroA* genes (or coding sequences) in combination with different promoters, transit peptides and other elements. The net result of all these attempts with Calgene's *aroA* genes was that the transformed plants had reduced susceptibility to glyphosate so that they could be termed to have partial resistance or tolerance, but no truly resistant or tolerant plants were ever identified. (DeRose Tr. 140-42; Lebrun Tr. 521-22; Comai Tr. 890-91).

RPA also determined that the B808 aroA gene was unstable in plants. (Freyssinet Tr. 621-22).

Most relevant to glyphosate resistance in corn, DeKalb, after years of effort, terminated all work with the Calgene bacterial EPSPS genes in 1993. (Spencer Tr. 1129-32; PTX-240, 241; DTX-1983 [last page]).

D. RPA Develops the Optimized Transit Peptide

A mutated EPSPS enzyme must be located within the site of its normal activity for it to work. That site is the chloroplast of a plant cell. In the mid-1980's researchers from various other companies demonstrated that the EPSPS must be connected to an element called the "transit peptide" in order to target the EPSPS into the chloroplast. (Lebrun Tr. 533, 535-36; DeRose Tr. 255, 302). In both wild-type (i.e., untransformed or natural) and transformed cells, the DNA must express a "precursor" polypeptide comprising both a transit peptide portion and an EPSPS enzyme portion. The transit peptide targets the precursor to the chloroplast, where the transit peptide effectively unlocks a channel in the chloroplast membrane by which the precursor enters into the chloroplast. Once in the chloroplast, the transit peptide is cleaved, leaving just the EPSPS enzyme — what is referred to as the mature protein. The EPSPS can then perform its enzymatic function. (DeRose Tr. 128-34).

As discussed in this trial and also detailed in the February 8, 2000 decision, RPA developed a chloroplast transit peptide for glyphosate resistance called the Optimized Transit Peptide or OTP.²

² The OTP is disclosed and claimed in United States Patent Number RE. 36,449, dated December 14, 1999, as a reissue of United States Patent No. 5,510,471. In the prior proceedings of this case, DeKalb had stipulated that its glyphosate resistant corn infringed this patent, and a jury had found (continued...)

The OTP contains DNA encoding the sunflower RuBisCo transit peptide fused to DNA encoding an N-terminal portion of a maize RuBisCo protein fused to DNA encoding the maize RuBisCo transit peptide. (DeRose Tr. 153-55). This OTP DNA sequence encodes the transit peptide portion of RPA's relevant EPSPS precursors. The function of the OTP is to target the EPSPS into the chloroplast, and once in the chloroplast to be cleaved cleanly to avoid any transit peptide residue on the mature EPSPS protein. (DeRose Tr. 155; Lebrun Tr. 508-15).

The OTP was invented by Michel Lebrun, Bernard Leroux and Alain Sailland, and was RPA's independent invention. (Lebrun Tr. 515-17; DTX-1257). Isolating the sequences for the transit peptide that ultimately became the OTP took a little more than one year's work. (Lebrun, Tr. at 514). Neither Dr. Comai nor anyone else at Calgene contributed to it. Dr. Comai did not contribute to the OTP, except for what had been already published and in the public domain, and did not provide any genetic material or design to RPA. (Lebrun Tr. 535-36, 560-62). (The Comai publication, of course, was cited as prior art in the prosecution of the OTP patent, and was not a bar to the grant of the patent.)

After the initial development of the OTP by the above inventors, Dr. DeRose further modified the OTP to create a "cleaner" sequence without potential restriction sites. Dr. DeRose did this specifically for the DeKalb collaboration and the modified OTP DNA sequence was provided to DeKalb. (DeRose Tr. 153, 161-62).

²(...continued)

that the patent was valid and not procured through inequitable conduct. The Court confirmed the jury findings in the February 8, 2000 opinion, which decision is now on appeal to the Federal Circuit. The issues here, however, are not dependent on the disclosure, infringement, validity or enforceability of the RPA patent, although the patent would further support the finding of the significance and novelty of RPA's contribution.

E. RPA Develops its Maize EPSPS Genes

In about 1986, independently of the Calgene collaboration, RPA undertook to create a glyphosate resistant corn line that, inter alia, could potentially be regenerated into glyphosate tolerant corn. (Freyssinet Tr. 591-92). Dr. Freyssinet had considered isolating the maize EPSPS gene from that culture early in 1989. (Freyssinet Tr. 613-14; PTX-1429 [at 031676]). With the termination of Calgene's efforts at the end of 1989, RPA accelerated its efforts to isolate that maize EPSPS gene from that special corn culture. (Freyssinet Tr. 625-26). The culture did not produce glyphosate resistant corn, but the culture had increased the concentration of EPSPS genes in the culture, which permitted RPA to now to isolate and EPSPS gene from that culture. (*Id.*).

After about two years of intensive effort, RPA was able to isolate an EPSPS gene from this culture, have it sequenced by the University of Texas, and undertake to have mutations introduced into the gene that were determined by RPA's scientists, but with the actual work to be performed by a RPA sister company by the name of Transgene, a contract laboratory specializing in such work. (Freyssinet Tr. 626-28; Lebrun Tr. 531-33).

RPA scientists, Drs. Lebrun, Sailland, and Freyssinet, decided to mutate their maize EPSPS gene to simulate the protein mutations that had been identified in the bacterial EPSPS — the published CT7 "101" mutation and the toxic "97" mutation of CT9/B808, and the "101" mutation identified by Monsanto in a published patent; and then make various "two-by-two" double combinations of these mutations. (Lebrun Tr. 525-28, 545, 548-49, 572-73). Dr. DeRose explained how the mutations were introduced. (DeRose Tr. 156-59). The mutations were made in RPA's unique maize EPSPS gene and RPA determined the specific DNA codons to simulate the amino acid mutations. (Lebrun Tr. 525-28, 572-73).

Dr. Comai did not have anything to do with RPA's development of its maize EPSPS genes. Dr. Comai's relevant work was all in bacteria, and he was not involved in RPA's efforts to develop its corn cell culture or decision to mutagenize the EPSPS of that culture, and Dr. Comai did not participate in any of RPA's efforts to isolate the corn EPSPS, mutate it, test it or further develop it. (Comai Tr. 886). In deciding what mutations to make in its maize gene, RPA utilized available information about amino acid mutations from published literature and what it had learned from CT9/B808, but the latter CT9/B808 mutation was toxic and it did not work to provide glyphosate resistance in plants. A mutation was developed by RPA in its maize gene to encode an equivalent change in the EPSPS enzyme to test for potential toxicity. As Dr. Lebrun testified:

A. The reason why we decided to use -- to introduce -- to translate the threonine to isoleucine mutation in the maize EPSPS gene is because this mutation was somehow toxic for the growth of bacteria expressing this kind of mutation and so we wanted to see whether it will be reproduced in a plant background. It was not because it was a source of resistance we use it in the first step of the mutagenesis of maize EPSPS gene.

(Lebrun Tr. 545). Initial laboratory tests indicated that some of the maize EPSPS genes were non-toxic and should be tested in plants.

F. RPA's Initial Collaboration With DeKalb

In 1991, in conjunction with Calgene's exit from glyphosate resistance work, RPA took over Calgene's responsibilities under a 1985 Development and Marketing Agreement between Calgene and DeKalb directed to developing Calgene's bacterial AroA gene for glyphosate resistance in corn. (Freyssinet Tr. 628-29) Consequently, RPA began a joint research collaboration with DeKalb. The first true technical meeting between the parties was on June 17, 1991. (DTX-290; Freyssinet Tr. 629).

The initial RPA and DeKalb collaborative efforts were directed at attempting to improve the DNA constructs comprising Calgene CT7 gene in an effort to make that gene work to provide glyphosate tolerance in DeKalb's corn. (DeRose Tr. 143, 145-46). RPA worked with DeKalb because RPA did not itself have the necessary know-how or manpower to transform or regenerate corn, and, therefore, it needed a partner to assist in developing its DNA constructs in corn. RPA worked primarily in molecular biology, and expended significant effort developing and evaluating genetic materials to confer glyphosate tolerance in corn. These constructs were developed and tested by RPA scientists at RPA's laboratory in Lyon, France, and other facilities. The nature of the collaboration was summarized by DeKalb's Dr. Emil "Buddy" Orozco as follows:

Q. And at some point did you begin working on a project that was a collaboration between DeKalb and Rhone-Poulenc Agrochemie?

A. Yes, I did.

Q. When was that?

A. I think it was around May or June of 1991.

Q. Can you describe for me the nature of that collaboration?

A. When the collaboration was initiated, the goal was to obtain transgenic maize that were resistant to glyphosate, and the division of work was that Rhone-Poulenc had glyphosate resistance genes or genes and regulatory elements, and DeKalb had the transformation expertise in corn.

Q. What was your understanding of Rhone-Poulenc's role in that collaboration?

A. My understanding was that they were providing the glyphosate resistance chain and some promoters and that they were doing some of the molecular biology work.

Q. What would DeKalb's role be?

A. And DeKalb's role was to provide the transformation expertise for maize, to put the appropriate DNA into maize and regenerate plants.

Q. When the collaboration began, did DeKalb already have the expertise to transform corn?

A. Yes.

Q. And what type of work did you personally perform as part of the DeKalb/RPA collaboration?

A. Well, I remember attending meetings and taking part in conversations and interacting with Rick DeRose in the design of various DNA vectors.

(Orozco Tr. 473-74). The lead scientists from both RPA and DeKalb testified that they worked closely together, collaborating in an attempt to develop glyphosate resistant corn. (*See, e.g.*, DeRose Tr. 142-55; PTX-46, 98). DeKalb's Dr. Orozco testified:

Q. How would you describe your working relationship with Dr. DeRose during the period of collaboration?

A. Oh, I would say it was an excellent relationship. A good collaboration.

(Orozco Tr. at 475).

Dr. DeRose worked with different promoters and with the OTP transit peptide, rather than using wild-type promoters and transit peptides, because he wanted to over-express the EPSPS in corn, rather than have normal expression, because he believed it was necessary to achieve agronomically acceptable levels of glyphosate resistance. (DeRose Tr. 160-61).

G. RPA Provides Maize EPSPS DNA Constructs to DeKalb

Preliminary laboratory tests indicated that the new maize genes were both resistant to glyphosate and worked normally. During a February 18, 1992 meeting between RPA and DeKalb, Dr. Freyssinet informed DeKalb that RPA had developed new maize EPSPS genes which worked in the lab and would be tested in plants in the field during 1992. Dr. Freyssinet indicated that the

new maize genes may be made available to DeKalb. (PTX-75 [at DKB040697]; Freyssinet Tr. 635-37).

RPA's limited field trials in 1992 were sufficiently promising that in November 1992, Dr. Freyssinet offered DNA constructs with RPA's new maize EPSPS genes to DeKalb for testing for glyphosate resistance in corn. (Freyssinet Tr. 637-38; DTX-1887).

From December 1992 to February 1993, Dr. DeRose worked to make DNA constructs containing the new maize genes for DeKalb. (DeRose Tr. 163-66; PTX-133, 142). Dr. Flick of DeKalb asked that RPA provide the new maize EPSPS in a form that could be attached to various promoters that RPA had previously supplied to DeKalb or which DeKalb had otherwise available, with which request Dr. DeRose complied. (DeRose Tr. 164-65; PTX-133). Therefore, in February 1993, Dr. DeRose sent DeKalb five DNA constructs, specifically for the purpose of DeKalb transforming corn to obtain transformation corn events that were glyphosate resistant, including:

- ▶ RD-125: a construct encoding Dr. DeRose's "cleaned-up" OTP, Methionine and 2xmzEPSPS, with a stop and a polylinker designed for easy attachment of promoters;
- ▶ RD-130: a complete expression cassette comprising RD-125 fused to the maize histone promoter and the adh1 intron; and
- ▶ RD-129 and 131: constructs equivalent to RD-125 and RD-130, but comprising RPA's single mutant maize EPSPS gene. (PTX-142; DeRose Tr. 165-68, 218-21, 419-20; Spencer Tr. 1137-40).

Dr. DeRose believed that RD-130 was the most promising construct he could make available to DeKalb for glyphosate resistance in corn. (DeRose Tr. 167-68). Dr. DeRose included a methionine between the OTP and 2xmzEPSPS in his constructs, in the hope of promoting stability

of the mature EPSPS enzyme in the plant cell. Admittedly, it is not known whether the methionine actually assists, but the DNA constructs with the methionine do work. (DeRose Tr. 344-45).

RPA provided its DNA constructs specifically for the purpose of DeKalb inserting them into the genome of corn to create transformation events that hopefully would be resistant to glyphosate. (DeRose Tr. 218-21).

H. DeKalb's Uses RPA's DNA Constructs for Glyphosate Resistant Corn

DeKalb made numerous corn transformations with RPA's constructs. The key transformation events, which are claimed in the 497 patent, contain the following DNA constructs or plasmids:

EVENT CLAIMED	DNA CONSTRUCT
GA21	Rice Actin Promoter; OTP; Met; 2xmzEPSPS; Nos
GG25	Maize Histone Promoter; mzadh1; OTP; Met; 2xmzEPSPS; Nos
GJ11	Hybrid 35S/Histone Promoter; OTP; Met; 2xmzEPSPS; Nos
FI117	Rice Actin Promoter; OTP; Met; 2xmzEPSPS; Nos; plus a Bar gene

The GG25 DNA construct was entirely made by Dr. DeRose, being his construct RD-130. (DeRose Tr. 221-22; PTX-142). The GJ11 DNA construct is Dr. DeRose's RD-125 fused to the hybrid 35S/Histone promoter that he had earlier provided to DeKalb. (DeRose Tr. 223-26; PTX-53, 142). The GA21 and FI117 transformation events contain RD-125 fused to a rice actin promoter and intron, whose origination is discussed below. (DeRose Tr. 238-39; PTX-142).

1. The 1994 Hawaii Field Trials: Success in the Field with Hybrid, Seed-Grown Plants

The above four transformation events were tested by DeKalb in September 1994 in field trials conducted in Hawaii. (DeRose Tr. 239-42; PTX-307, 317). At that point, the transformation events had been crossed to another corn line, and the resulting hybrid corn was tested. The tests demonstrated that the hybrid corn containing the four transformation events was resistant to application of glyphosate at 16 oz per acre — i.e., suffered no adverse affects — while corn plants otherwise similar but not containing the transformation events were either killed or significantly harmed. (*Id.*).

2. Roundup Ready Corn: Success at Dekalb With RPA Genes

Unbeknownst to RPA until 1997, the genes that RPA provided to DeKalb during the course of the collaboration were successfully inserted into corn by DeKalb, and corn tolerant to commercial levels of glyphosate was created. DeKalb received approval from the federal governing authorities to commercialize the corn, known as GA21 "Roundup Ready" corn. DeKalb began selling this product in 1998, and by all measures it has been very successful.

I. The Rice Actin Promoter

The GA21 and FI117 transformation events contained RD-125 attached to the rice actin promoter. The rice actin promoter was invented by Dr. Ray Wu of Cornell University. RPA, however, first suggested to DeKalb that the rice actin promoter and intron be used to promote an EPSPS gene. This is demonstrated by the minutes of the June 17, 1991 meeting between Dr. Freyssinet and various DeKalb scientists, including Drs. Catherine Mackey, Chris Flick, Emil

"Buddy" Orozco, and Michael Spencer. (Freyssinet Tr. 630-34; DTX-290). The minutes of the meeting (DTX-290) provide under the section entitled "RPA aroA progress report" the following:

Other constructs under testing were discussed (See Attachment 4).

* * *

- Actin 1 promoter from rice (obtained from Ray Wu) shows 10-30x higher transient expression than CaMV-adh intron 1 and 100-300x higher expression than CaMV alone. This was measured in BMS and embryogenic cell suspensions using CAT as a marker.

"Attachment 4" referred to in the minutes is a RPA handout during the meeting that states in part:

OTHER CONSTRUCTS UNDER TESTING

* * *

2000BP Promoter Fragment from Rice Actin1 (including First Intron)/OTP/CT7/NOS3'

As shown at trial, this proposed construct describes exactly the DNA construct of GA21, except that the CT7 is substituted with the 2xmzEPSPS gene (including the methionine). (Freyssinet Tr. 633-34; Spencer Tr. 1150). There is no evidence that anyone at DeKalb had thought of using the rice actin promoter in conjunction with an EPSPS gene before this meeting.

J. The Failure of Others

DeKalb's expert Dr. Quatrano admitted:

Q. . . . Can you identify for the jury any DNA construct that was disclosed in the literature in patents, wherever else publicly available prior to April of 1990, which DNA construct was eventually shown to provide glyphosate resistance in corn?

A. I don't believe that I can point to that evidence.

(Quatrano Tr. 1025). The significance of RPA's contribution is further demonstrated by Monsanto's failure to develop glyphosate resistant corn. RPA presented the testimony of Dr. Charles Armstrong

and Dr. Steven Padgett during the trial. This testimony demonstrated Monsanto's failure to develop glyphosate resistant corn.

During the 1980's and early 1990's, Monsanto was the world leader in plant biotechnology. (Padgett Tr. at 489). In its attempt to create glyphosate resistant corn, Monsanto made millions of mutations in EPSPS genes. (Armstrong Tr. at 489). According to Dr. Armstrong:

Q. And is it fair to say that in order to find the right mutated gene to use in creating RoundUp Ready crops, Monsanto made literally millions of mutations in these enzymes and screened those for their glyphosate tolerance characteristics?

A. We've done a lot of mutation and screening work of EPSP synthase genes, that is correct.

Q. Is it fair to say that Monsanto literally did millions of mutations in these enzymes?

A. I believe in terms of the bacterial screening work, that's probably correct.

(Armstrong Tr. 489; *see also* Padgett Tr. 584). However, Monsanto never made the two mutations that are found in DeKalb's Roundup Ready® Corn. (Padgett Tr. 584-85). Notwithstanding the strength of and resources available to its research program, Monsanto had never heard of the OTP or RPA's double mutant maize gene. (Armstrong Tr. 493-94).

Even in 1996, Monsanto did not have Roundup Ready Corn that it was willing to commercialize. (Padgett Tr. 586). To the contrary, GA21 was the event of choice. (Armstrong Tr. 483-84; PTX-674). It was the event that was commercialized and Monsanto informed its licensees of that fact. (Armstrong Tr. 499; PTX-568).

Indeed, in the 497 patent itself, DeKalb asserted:

The ultimate goal in producing transgenic glyphosate resistant maize plants is to provide plants which may be treated with glyphosate at a level sufficient for killing weeds, without a deleterious effect on yield or fertility. In this respect, the prior art

has failed. There is, therefore, a great need in agriculture for maize plants which can be directly sprayed in the field with glyphosate, thereby killing weeds, but otherwise not producing a deleterious effect on the crop itself.

(497 pat., col. 2 lines 45 to 53) (emphasis added).

K. DeKalb's Recognition of the Significance of RPA's Achievement

DeKalb itself recognized the significance of RPA's contribution. For example, DeKalb suspended all work involving the *aroA* construct and informed RPA that the double mutant was the key to success in providing glyphosate resistance. (DeRose Tr. 208-10; PTX-241). DeKalb further recognized the significance of RPA's contribution when it commercialized Roundup Ready® corn based on RPA's genetic materials. (DeRose Tr. 211-12; PTX-1390; PTX-1392). In fact, RPA's DNA construct is in every cell of every corn plant that has or is growing on millions of acres that comprise Roundup Ready® corn. (DeRose Tr. 104).

Michael Spencer and DeKalb also recognized RPA's contribution, and that they arose out of the parties' collaboration, in various actual or proposed scientific papers. Thus, Spencer wrote to Dr. DeRose in December 1996, stating:

DeKalb has developed transgenic maize lines using a mutant maize EPSPS gene provided by Rhone-Poulenc under terms of the DeKalb/RPA collaboration on glyphosate tolerant maize that have shown commercial levels of tolerance to RoundUp.

(DeRose Tr. 212; PTX-1392). DeKalb proposed that Drs. DeRose and Freyssinet be listed as co-authors on the publication of the achievement of glyphosate resistant corn. (DeRose Tr. 212-14; PTX-1403; PTX-1407; PTX-1412). Mr. Spencer also acknowledged RPA's contribution in a scientific meeting, in which he stated:

[I]t was made clear to the audience that the EPSPS genes, the chloroplast transit peptide sequence and various promoters were provided to DeKalb by Rhone-Poulenc

as a part of a research collaboration. Rick DeRose and Georges Freyssinet were acknowledged for their contributions.

(DeRose Tr. 215; PTX-1412).

At trial, DeKalb emphasized that it transformed the corn and developed the transformation events. RPA never disputed this; indeed, RPA has always acknowledged this, noting that DeKalb's expertise in those areas is why RPA entered into a collaboration with DeKalb in the first place. However, DeKalb's expertise in these areas is not relevant to the inventorship determination. That is why it's scientists are co-inventors. The plain language of 35 U.S.C. § 116 precludes the court from weighing the relative contributions of RPA's and DeKalb's scientists, so long as their contributions were significant, which they clearly were, as discussed *infra*.

L. The 497 and 798 Patents

1. The Lundquist 798 Patent

DeKalb filed a first patent application on January 22, 1990, followed by a continuation in part application on April 11, 1990, followed by a continuation application Serial Number 441,073 on May 15, 1995, which matured into the 798 patent. Claim 1 of the 798 patent, which is the only independent claim of the 798 patent, reads as follows:

A fertile transgenic *Zea mays* plant containing an isolated heterologous DNA construct encoding EPSP synthase wherein said DNA construct is expressed so that the plant exhibits resistance to normally toxic levels of glyphosate, wherein said resistance is not present in a *Zea mays* plant not containing said DNA construct, and wherein said DNA construct is transmitted through a complete normal sexual cycle of the transgenic plant to the progeny generation.

2. The Spencer 497 Patent

The 497 patent was filed as U.S. 832,078, on April 3, 1997. It has 63 claims. Claim 46 of the 497 patent is as follows:

46. A glyphosate resistant, hybrid maize plant comprising a chromosomally integrated expression cassette comprising (a) a modified maize EPSPS gene encoding an EPSPS protein having isoleucine at position 102 and serine at position 106 and (b) a promoter active in maize operably linked to said EPSPS gene, wherein said hybrid maize plant comprises a transformation event selected from the group consisting of GA21, seed comprising said GA21 transformation event having been deposited as ATCC Accession Number 209033, FI117, seed comprising said FI117 transformation event having been deposited as ATCC Accession Number 209031, GG25, seed comprising said GG25 transformation event having been deposited as ATCC Accession Number 209032, and GJ11, seed comprising said GJ11 transformation event having been deposited as ATCC Accession Number 209030.

III. GENERAL LAW OF JOINT INVENTORSHIP

The key provisions of the patent laws here in issue are:

Sec. 116. Inventors

When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent. * * *

Sec. 256. Correction of named inventor

Whenever . . . through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issued a certificate correcting such error.

The error of omitting inventors . . . shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

Sec. 262. Joint owners

In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States,

or import the patented invention into the United States, without the consent of and without accounting to the other owners.

The law of joint inventorship has been well-explained in several recent Federal Circuit cases.

In *Pannu v. Iolab Corp.*, 155 F.3d 1344 (Fed. Cir. 1998), the Federal Circuit summarized the law of joint inventorship as follows:

All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.

155 F.3d at 1351 (citations omitted).

In *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456 (Fed. Cir.), *cert. denied*, 525

U.S. 923 (1998), the Federal Circuit extensively reviewed the precedents and explained the law as follows:

A patented invention may be the work of two or more joint inventors. Because “[c]onception is the touchstone of inventorship,” each joint inventor must generally contribute to the conception of the invention. “Conception is the ‘formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.’” An idea is sufficiently “definite and permanent” when “only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.”

The conceived invention must include every feature of the subject matter claimed in the patent. Nevertheless, for the conception of a joint invention, each of the joint inventors need not “make the same type or amount of contribution” to the invention. Rather, each needs to perform only a part of the task which produces the invention. On the other hand, one does not qualify as a joint inventor by merely assisting the actual inventor after conception of the claimed invention. One who simply provides the inventor with well-known principles or explains the state of the art without ever having “a firm and definite idea” of the claimed combination as a whole does not qualify as a joint inventor. Moreover, depending on the scope of a patent’s claims, one of ordinary skill in the art who simply reduced the inventor’s idea to practice is

not necessarily a joint inventor, even if the specification discloses that embodiment to satisfy the best mode requirement.

Furthermore, a co-inventor need not make a contribution to every claim of a patent. A contribution to one claim is enough. Thus, the critical question for joint conception is who conceived, as that term is used in the patent law, the subject matter of the claims at issue.

35 U.S.C. § 256 provides that a co-inventor omitted from an issued patent may be added to the patent by a court "before which such matter is called in question." To show co-inventorship, however, the alleged co-inventor or co-inventors must prove their contribution to the conception of the claims by clear and convincing evidence. However, "an inventor's testimony respecting the facts surrounding a claim of derivation or priority of invention cannot, standing alone, rise to the level of clear and convincing proof." The rule is the same for an alleged co-inventor's testimony. Thus, an alleged co-inventor must supply evidence to corroborate his testimony. Whether the inventor's testimony has been sufficiently corroborated is evaluated under a "rule of reason" analysis. Under this analysis, "[a]n evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the [alleged] inventor's story may be reached."

135 F.3d at 1460-61 (citations omitted).

In *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466 (Fed. Cir. 1997), the Federal Circuit stated:

The issue of joint inventorship is governed by 35 U.S.C. § 116

This provision sets no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor. Rather, a joint invention is simply the product of a collaboration between two or more persons working together to solve the problem addressed. The determination of whether a person is a joint inventor is fact specific, and no bright-line standard will suffice in every case.

Nonetheless, our precedent provides guidance as to what types of acts are, or are not, sufficient in quantum and quality to establish joint inventorship. One need not alone conceive of the entire invention, for this would obviate the concept of joint inventorship. However, a joint inventor must contribute in some significant manner to the conception of the invention. As such, "each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice."

If a person supplies the required quantum of inventive contribution, that person does not lose his or her status as a joint inventor just because he or she used the services, ideas, and aid of others in the process of perfecting the invention. However, those others may also in appropriate circumstances become joint inventors by their contributions. In addition, a person is not precluded from being a joint inventor simply because his or her contribution to a collaborative effort is experimental.

The basic exercise of the normal skill expected of one skilled in the art, without an inventive act, also does not make one a joint inventor. Therefore, a person will not be a co-inventor if he or she does no more than explain to the real inventors concepts that are well known and the current state of the art. The case law thus indicates that to be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention.

123 F.3d at 1473. See also *Hess v. Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976 (Fed. Cir.), cert. denied, 520 U.S. 1277 (1997); *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223 (Fed. Cir. 1994), cert. denied, 515 U.S. 1130 (1995); *Sewall v. Walters*, 21 F.3d 411 (Fed. Cir. 1994); *Kimberly-Clark Corp. v. Proctor & Gamble Distrib. Co.*, 973 F.2d 911 (Fed. Cir. 1992); *MCV, Inc. v. King-Seeley Thermos Co.*, 870 F.2d 1568 (Fed. Cir. 1989).

"[C]orrection of nonjoinder of entitled inventors does not invalidate a patent." *University of Colorado Foundation, Inc. v. American Cyanamid Co.*, 196 F.3d 1366, 1375 (Fed. Cir. 1999), cert. denied, 120 S. Ct. 2005 (2000).³

IV. JOINT INVENTORSHIP OF THE SPENCER 497 PATENT

A. Interpretation of Claim 46 of the 497 Patent

³ There was no evidence presented by either party that the failure to name the correct inventors was deceptive, and, therefore, good faith is presumed. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1350 n.4 (Fed. Cir. 1998) ("While lack of deceptive intent, as a negative, may be hard for a patentee to prove when it claims relief under the statute, good faith is presumed in the absence of a persuasive showing of deceptive intent."). In such circumstances, the court is required to correct the naming of inventors. *Pannu*, 155 F.3d at 1350 (Fed. Cir. 1998).

The parties stipulated to the construction of claim 46 of the 497 patent. Given the positions and arguments of the parties, only two constructions need be mentioned. The stipulated legal construction of the term “transformation event” is “a plant or seed which has a specific DNA cassette in a specific location somewhere within the chromosome of the corn cell.” The stipulated legal construction of the term “hybrid corn plant” is “a cross of two different types of genotypes of corn, which are sometimes called the parents of the hybrid corn plant.”

B. RPA Scientists Significantly Contributed to the Conception of Claim 46 During the Parties’ Collaboration

As detailed in the Factual Background, RPA submitted essentially undisputed evidence, substantially confirmed by DeKalb’s Michael Spencer, that in February 1993, RPA’s Drs. Rick DeRose and Georges Freyssinet provided DNA constructs or plasmids to DeKalb; that they did so specifically for the purpose of having DeKalb use its existing know-how to transform corn to obtain corn transformation events that were glyphosate resistant; that RPA submitted the DNA constructs as part of a collaborative effort between the parties; that DeKalb then used RPA’s constructs exactly as intended — to transform corn, and isolated the four transformation events that are claimed in claim 46; and that corn lines of the four events were first field tested in September 1994 in Hawaii, and were thereafter further developed by DeKalb.

DeKalb did not design the “RD-125” portion of the DNA constructs of the claimed transformation events. Further, RPA designed the entirety of the DNA construct of GG-25, provided to DeKalb the promoter for event GJ11, and introduced the use of the rice actin promoter with EPSPS genes. DeKalb does not suggest that RPA responded to some detailed specification by DeKalb, or that it had any input into any aspect of RPA’s constructs, except for the dispute for the

origination of the rice actin promoter and intron in two of the transformation events. RPA developed the DNA constructs on its own and without any assistance by DeKalb. (DeRose Tr. 421-22, 462).

DeKalb also does not dispute that RPA provided the DNA constructs to DeKalb for corn transformation to develop glyphosate resistant corn at a time that the parties were in a collaboration. During the collaboration, DeKalb received the genes and transformed corn to obtain the transgenic events claimed in the 497 patent. (Spencer Tr. 1059-71; DTX-508, 2022; PTX-261).

RPA's contributions to the 497 patent are enormous and undeniable. RPA provided those genes to DeKalb for express purpose of creating fertile glyphosate resistant corn, precisely what is claimed in the 497 patent. (DeRose Tr. 220-21; Spencer Tr. 1139-40). All four claimed transgenic corn events contain RPA's genes, but for which the claimed transformation events would never have existed. (DeRose Tr. 106, 219-21, 420-21; Spencer Tr. 1126-27; PTX-142).

Finally, the significance of RPA's contribution is demonstrated by the fact that the constructs worked. As Dr. DeRose testified without contradiction:

Q. ... [P]rior to RPA providing the DNA constructs to DeKalb, had anyone ever put a combination of promoters, introns, chloroplast transit peptides and EPSPSs that provided glyphosate resistance in corn so that the corn was not adversely impacted when glyphosate was applied?

A. Prior to our collaboration with DeKalb, I think we were the only ones who had developed a construct that provided glyphosate tolerant corn.

(DeRose Tr. 427-28). In short, the DNA constructs created by RPA and provided to DeKalb were unequivocally critical aspects of glyphosate resistant corn and the claimed transformation events.

Therefore, the jury's determination that DeKalb's named inventors did not alone conceive the entire scope of the subject matter of claim 46 is not only justified, but the only reasonable conclusion, and should be followed by the Court.

DeKalb, nevertheless, apparently argues that the RPA's scientists are not joint inventors, because their contributions were "well-known and state of the art"; that patent applications after September 1994 disclosed RPA's DNA constructs; and that the only novelty of claim 46 resides in the locus of the DNA constructs in the chromosome of the corn plants, to which RPA did not contribute. Each of these arguments is deficient on the facts and the law.

C. RPA's Contributions Were Not Well-Known or Current State of the Art

RPA's contribution to claim 46 was plainly more than providing publicly available scientific literature, describing what was then available in the marketplace, or explaining public domain the material or well-known and the current state of the art. The RPA constructs were secret proprietary developments at the time they were introduced into corn as part of the RPA-DeKalb collaboration.

Dr. DeRose testified:

Q. Now as of September 1994, were any of the maize double mutant EPSP DNA constructs that you had sent to DeKalb in 1993, ever been disclosed anywhere in publications or otherwise in the public domain?

A. No. DNA constructs that I sent to DeKalb at the beginning of 1993, were still RPA proprietary trade secret.

(DeRose Tr. 243). Similarly, Dr. Quatrano admitted that the specific constructs claimed in the 497 patent were not publicly available as of September 1994. (Quatrano Tr. 1013, 1015-17).

DeKalb apparently argues, nevertheless, that RPA's contributions were commonly known or equivalent to providing mere "public domain" materials because (a) RPA's work allegedly derived from the work of Dr. Luca Comai, and (b) the alleged similarity of RPA's 2xmzEPSPS gene to that disclosed by Monsanto in a 1988 foreign patent publication. It also submitted a "proffer" of

two publications that the Court had excluded at trial, arguing that they are "prior art" demonstrating the lack of novelty of RPA's contribution.

For reasons detailed below, however, none of DeKalb's arguments are meritorious on the facts, even were DeKalb entitled to raise alleged "obviousness."

1. No Relevant Input by Dr. Comai

DeKalb's arguments are legally irrelevant, because DeKalb relies on a non-existent "obvious to a person of ordinary skill in the art" test. DeKalb has cited no authority for the proposition that a joint inventors contribution must pass the "non-obviousness" standard such as presented by 35 U.S.C. § 103, and the proposition flies in the face of the above-cited governing standards defining joint inventorship. Nothing in the statutes or the governing authority requires a joint inventor to pass an "non-obviousness" litmus test. The law delineates only that RPA contribute to the conception of a claim something that is more than "well known and the current state of the art." *Pannu*, 155 F.3d at 1351.

Dr. Freyssinet testified:

Q. . . . What if anything did Dr. Comai and Calgene contribute to the DNA constructs that you have that appear on PTX-1450?

A. On the construct, nothing.

Q. Did Dr. Comai and Calgene provide any contribution to you or anyone else at RPA, to your knowledge, in the development of the OTP from the information that they had published or compared to the information that was already published as to their transit peptides?

A. No.

Q. Did Dr. Comai . . . or anyone else at Calgene, contribute anything to RPA's development of the maize EPSPS genes?

A. On the maize DNA, nothing.

(Freyssinet Tr. 749-50).

On the basis of the above facts, it cannot be said that Dr. Comai contributed to RPA's DNA constructs containing the 2xmzEPSPS.⁴ The CT7 "101" mutation was already published by 1985,

⁴ The trial testimony of Drs. Freyssinet and Comai are mostly consistent regarding the collaboration between RPA and Calgene. The few differences reflect Dr. Comai's attempt to take credit for greater input into the development of RPA's 2xmzEPSPS gene. (Typical is Dr. Comai's testimony about page 25 of his laboratory notebook, DTX-1497, which shows his effort to synthesize a "97" plus "101" mutation in *aroA*. (Comai Tr. 864). The lab notebook page is dated May 11, 1989, which is consistent with Dr. Freyssinet's testimony that the Scientific Committee decided in April 1989 to have Dr. Comai synthesize the gene. (Freyssinet Tr. 609-12; PTX-1429 [at 031675]). To the extent that there are differences in the testimony, it is noted that Dr. Freyssinet's testimony is completely consistent with and corroborated by contemporaneous documents, while Dr. Comai's testimony goes beyond any corroborating document. In such case, the requirement of corroboration should be applied. For example, Dr. Comai testified at length that he and RPA representatives discussed plant EPSPS genes at their meetings. (Comai Tr. 876-81). Yet, the detailed records of all the RPA-Calgene meetings do not reflect any such discussions, except for one note by Dr. Freyssinet that he may have mentioned RPA's contemplated effort to isolate the maize EPSPS gene. (Freyssinet Tr. 613-14; PTX-1429 at 031676).

Patent law has consistently dictated a high standard of proof to support alleged conception of an invention. In *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572 (Fed. Cir. 1996), the court held:

This court has developed a rule requiring corroboration where a party seeks to show conception through the oral testimony of an inventor. This requirement arose out of a concern that inventors testifying in patent infringement cases would be tempted to remember facts favorable to their case by the lure of protecting their patent or defeating another's patent. While perhaps prophylactic in application given the unique abilities of trial court judges and juries to assess credibility, the rule provides a bright line for both district courts and the PTO to follow in addressing the difficult issues related to invention dates.

In assessing corroboration of oral testimony, courts apply a rule of reason analysis. Under a rule of reason analysis, "[a]n evaluation of all pertinent evidence must be made so that a sound determination of the credibility of the inventor's story may be reached."

(continued...)

and, therefore, was mere published prior art. (Comai Tr. 854-55 ; Comai Ex. 10; DX 129). The "97" mutation of B808 was a product of routine random mutagenesis that was requested by the Scientific Committee that included Dr. Freyssinet, and, in any event, Calgene had demonstrated that the "97" mutation was not only ineffective in providing glyphosate resistance, but was toxic. Moreover, Dr. Comai's relevant work was all in bacteria, and there is no evidence that Dr. Comai had any involvement in RPA's efforts to develop its corn cell culture, decision to mutagenize the EPSPS of that culture, or participated in any of RPA's efforts to isolate the corn EPSPS, mutate it, test it or further develop it.

Ultimately, the indisputable point is that any change in an enzyme can have profound consequences, and any difference in the DNA codons encoding that change can also have profound effects. Indeed, Dr. Comai himself testified:

Q. Is it correct, Dr. Comai, that changing a single amino acid in an enzyme can have a dramatic effect on how an enzyme functions?

A. It's correct to say that amino acid change can change an enzyme.

Q. Is that because a single amino acid change or substitution can change a critical point of orientation within that EPSP synthase structure?

A. Well, there are many reasons why a single amino acid change can change the structure. It may have to do with hydrophobic/hydrophilic interactions. It may have to do with steric interactions. It may have to do with disrupting the type of secondary structures such as alpha helix or beaded sheets. So many reasons. We're getting into relatively complex protein biochemistry field.

⁴(...continued)

79 F.3d at 1577 (citations omitted). See also *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1474 (Fed. Cir. 1997) ("Of course, every putative inventor must nonetheless provide corroborating evidence of any asserted contributions to the conception of the invention. Like conception of the entire invention, a contribution to conception is a mental act which cannot be accurately verified without corroboration.").

Q. Do you know whether the substitution that you created in CT7 encoded an EPSP synthase that had different secondary structure than the wild-type EPSP synthase enzyme?

A. I don't know.

(Comai Tr. 883-84).

Beyond the OTP and 2xmzEPSPS, the DNA constructs that RPA provided to DeKalb generally also included promoters, enhancer or intron sequences in some cases, and a methionine (or "met") encoding codon between the OTP and 2xmzEPSPS coding sequences. DeKalb does not even suggest that Dr. Comai — or anyone else — had any involvement in the design of those material combinations.

In short, while there had been a collaboration between Calgene and RPA, and direct communications between Dr. Freyssinet and Dr. Comai, there is no evidence that Dr. Comai contributed anything to the development of the OTP and the 2xmzEPSPS other than information that was published, and that "prior art" did not in any way disclose or render obvious or otherwise detract from the plain fact that both the OTP and 2xmzEPSPS genes were invented and developed by RPA's scientists without any assistance from Dr. Comai.

2. Monsanto's 1988 Patent Publication

DeKalb stressed at trial a 1988 Monsanto patent publication, No. 0 293 358 (DTX-1940; the "1988 Monsanto publication"). The publication demonstrates only the failure of others, the critical sensitivity of what may initially appear to be small differences in genetic materials, and the significance and novelty of RPA's contribution to glyphosate resistant corn.

The 1988 Monsanto publication disclosed: (a) EPSPS amino acid sequences from three plants, including the EPSPS found in maize; (b) a technique for isolating an EPSPS gene from

plants, although the technique would require up to a year's effort (Quatrano Tr. 1002-05; DTX-1940); and (c) that modifying the EPSPS DNA to encode a protein having an alanine instead of glycine at position 101 would provide for glyphosate resistance in plants. (DeRose Tr. 168-70, 312-17; Quatrano Tr. 1006-07; DTX-1940).

DeKalb's reliance on the 1988 Monsanto publication is misplaced. First, Monsanto did not disclose its gene in that publication. The 1988 Monsanto publication discloses only about 2% of the DNA nucleotide sequence of that Monsanto maize EPSPS gene. (Quatrano Tr. 1006-07; DeRose Tr. 314). Therefore, one skilled in the art would still have to deduce the remaining sequences.

Second, there is only evidence that Monsanto's maize EPSPS gene never provided glyphosate resistance in corn. Specifically:

- ▶ The maize EPSPS gene disclosed in the 1988 Monsanto publication has never been shown to provide any glyphosate resistance in corn, and, in fact, has never been published after this publication. (DeRose Tr. 169-70, 429, 435-36; Quatrano Tr. 1012). Dr. Quatrano admitted as much:

Q. Now, do you have any information and specifically documentation, that the maize gene that Monsanto described as opposed to the RPA version of that maize gene, provided glyphosate resistance in corn? Other than whatever you may say about RPA's gene?

A. No, I don't believe so.

(Quatrano Tr. 1012-13).

- ▶ Monsanto admitted that its maize EPSPS genes in general never provided adequate glyphosate resistance in corn. (Section II.J., *supra*).

▶ A later Monsanto patent taught that the glycine to alanine 101 mutation disclosed in the 1988 Monsanto publication was insufficient to provide glyphosate resistance. (DeRose Tr. 430, 433-35; PTX-1421).

▶ Even if, hypothetically, Monsanto's maize EPSPS gene could provide glyphosate resistance in corn transformed with the necessary DNA construct, there is nothing in the 1988 Monsanto publication that discloses any such suitable DNA constructs for glyphosate resistance in corn. (DTX-1940). DeKalb has not pointed to any such disclosure in the publication.

Third, even if a Monsanto maize EPSP gene was deemed disclosed and it was concluded that the gene could hypothetically provide glyphosate resistance in corn, RPA's single mutant gene and DNA constructs are necessarily different from Monsanto's version, because:

▶ There are three amino acid differences between Monsanto and RPA's respective wild-type maize genes (i.e., before any intentional mutation). (DeRose Tr. 435; Lebrun Tr. 563-64).

▶ RPA's single mutant maize EPSPS gene used in RPA's DNA constructs had a different codon for coding the alanine 101 mutation in the EPSPS enzyme, which RPA believed would be more preferred in corn plants. (DeRose Tr. 431-33).

▶ Monsanto's 1988 publication does not disclose or teach either RPA's 2xmzEPSPS gene, any of the promoters used with RPA's DNA constructs, RPA's OTP transit peptides, or the DNA constructs RPA provided to DeKalb. (Quatrano Tr. 1010-21; DTX-1940).

▶ Although the 1988 Monsanto publication mentions a natural transit peptide attached to the EPSPS, there is no evidence that those transit peptides would function similarly to the OTP. (Quatrano Tr. 1010-11; DTX-1940).

Because of the significant differences between the RPA and Monsanto versions of the single mutant maize EPSPS gene, it is not appropriate to attempt to use tests with RPA's single mutant maize gene, in RPA's DNA's constructs, as evidence that the Monsanto 1988 publication disclosed DNA constructs for glyphosate resistance in corn. (*Cf.* Quatrano Tr. 1011-12).

Therefore, the 1988 publication of Monsanto's version of a single mutant maize EPSPS gene does not disclose a glyphosate resistance gene useful in corn, and does not disclose any operable DNA constructs for glyphosate resistance in corn. Even if it did, RPA's single mutant EPSPS gene was different from anything disclosed in the 1988 Monsanto publication, as were RPA's DNA constructs. Finally, the so-called "101" mutation of the 1988 Monsanto publication is not used in any of the 497 patent constructs. (DeRose Tr. 462-63).

There is no evidence that the Monsanto patent disclosed the 2xmzEPSPS or any of the specific constructs given to DeKalb. In fact, the evidence overwhelmingly showed that the gene disclosed in the Monsanto patent could not provide glyphosate resistance at all. Thus, the Monsanto patent cannot detract from or render "obvious" RPA's significant contribution to claim 46 of the 497 patent.

3. RPA's 1997 PCT Publication and DeKalb's 1995 PCT Publication

DeKalb argues that RPA's contributions to claim 46 of the Spencer patent are inconsequential for purposes of 35 U.S.C. § 256 because DeKalb allegedly published, on March 2, 1995 "the construct that forms the basis for RPA's joint inventorship claim" in its 1995 PCT patent application (DTX-1661; Tab 20 to DeKalb's Proffer), and that RPA allegedly published its DNA constructs on February 6, 1997, as part of RPA's 1997 PCT patent application (DTX-1488; Tab 19

to DeKalb's Proffer). This argument is faulty for several reasons, and the Court properly excluded such evidence at trial.

a. Reduction to Practice of Claim 46 of the 497 Patent

Preliminarily, to the extent that the date of reduction to practice were to be relevant to any issue, claim 46 was reduced to practice in September 1994. (DeRose Tr. 239-43; PTX-307, 317). DeKalb argues only that the Hawaii field trial did not involve "hybrid corn." Yet, the parties stipulated that "a hybrid corn plant is a cross of two different genotypes of corn which are sometimes called the parents of the hybrid corn plant." The Hawaii tested corn plants were manifestly hybrids by this stipulated definition because they were a cross of two different genotypes of corn AT824 and LH132. (DeRose Tr. 1365-68) All four claimed events were created by transformation of corn tissue derived from corn line AT824. (DeRose Tr. 1366; PTX-317; JTX-1, 497 patent Examples 2 and 3). AT824 is a B73-derived inbred corn line. (497 patent, Example 1; DeRose Tr. 1365-68; PTX-1458, 1460). The regenerated plants were crossed to corn line LH132. (DeRose Tr. 1365-68; PX-317). Seeds from the corn were then planted at DeKalb's Hawaii field testing facility. The corn plants grown from the AT824 x LH132 crossed seeds were by definition hybrids.⁵

The four transformation events and other otherwise similar plants were tested in September 1994 by being sprayed with glyphosate at the rate of 16 ounces of Roundup® per acre, which is a

⁵ DeKalb's witness, Dr. Rita Mumm, admitted that the Hawaii corn plants were derived from a cross of the AT824 and LH132 corn lines, but, nevertheless, argued that the corn was not hybrid, because both AT824 and LH132 were from the same heterotic group. (Mumm Tr. at 1346-47). Her testimony, however, is self-contradictory, because she admitted that "genotype" means "genetic make up", and then also admitted that any corn that is bred from two different parents, even if related, is a different genotype from both those parents. (*Id.* at 1351 ("Q. Can you answer my question yes or no, does it have the same genotype? A. Well, no.")).

commercially effective dose. DeKalb's test report demonstrates that the four transformation events were not harmed at all by the glyphosate application while otherwise similar (control) plants were either killed or adversely affected at the same rate of application. (DeRose Tr. 239 - 243; PTX- 307; PTX-317) The corn tested in the Hawaii September 1994 trials met every element of claim 46. (DeRose Tr. 239 - 243; PX-317). Claim 46 was, therefore, reduced to practice by September 1994.⁶

b. The 1995 and 1997 PCT Publications Are Legally Irrelevant

DeKalb's argument that the Court should consider the 1995 and 1997 PCT Publications is erroneous as a matter of law. The Federal Circuit has established that an inventor's contribution is determined as of *the date that the contribution was made*, not the date of the filing of the invention. In *Pannu v. Iolab Corp.*, 155 F.3d 1344 (Fed. Cir. 1998), the Federal Circuit specifically considered and dismissed as legally irrelevant an argument almost identical to that by DeKalb. Specifically, Iolab argued that its inventor, Link, should not only be added as an inventor of a patent, but that the named inventor, Pannu, should be thrown off the patent on the ground that Pannu had already disclosed his contribution to the invention publically more than a year before they had started working together. Therefore, like DeKalb here, Iolab and Link argued that Pannu was not a joint

⁶ DeKalb argues that claim 46 could not have been conceived until it was "reduced to practice." See *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991). (It is not clear what the Federal Circuit was referring to as a "reduction to practice" in such cases — i.e., whether it was shorthand for "made and identified" or requiring also demonstration of suitability for intended purpose.) However, the concept of simultaneous conception and reduction to practice has no bearing on whether RPA's inventors contributed to that simultaneous conception and reduction to practice. *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466 (Fed. Cir. 1997) ("However, the doctrine [of simultaneous conception and reduction to practice] cannot be used, as the district court did here, to show that because the first person did not conceive or reduce to practice the entire claimed invention, he or she did not at least contribute in some significant way to the ultimate conception.")

inventor because his contribution was in the prior art. The Federal Circuit dismissed the argument as irrelevant:

Iolab asserts that because Pannu placed his contribution in the prior art more than one year before he met with Link in 1980 . . . Pannu cannot even claim the status of joint inventor. Iolab is mistaken. It is undisputed that Pannu and Link collaborated in the development and production of one-piece prototype embodiments of the invention. Link cannot claim the status of a sole inventor simply because Pannu had disclosed his ideas to Link and others more than a year earlier. During the meeting with Link, Pannu was doing more than simply providing Link with well-known principles or explaining the state of the art; he was contributing his ideas concerning the snag-resistant elements to a total inventive concept. Because it is undisputed that the invention was conceived while Link and Pannu were engaged in a collaborative enterprise and it is furthermore undisputed that Pannu conceived significant aspects of the invention, Pannu is certainly at least a co-inventor.

Pannu v. Iolab Corp., 155 F.3d at 1351.

Here, DeKalb not only attempts to include alleged "prior art" that is after the inventors' contribution, but is after the reduction to practice of the invention. No authority cited by DeKalb even comes close to justifying such an argument.

Second, DeKalb's argument is self-contradictory. Claim 46 can be viewed as a combination of three elements: DNA construct, transformation and regeneration, and crossing the regenerant with another line to make a hybrid. Hybrid corn is, of course, nothing new, and DeKalb admitted in its Pre-Trial Brief (Doc. #624) that the transformation and regeneration steps used to create the transformation events were prior art as of the filing date of the 497 patent application:

Not only were the genetic components of the claimed transformation events old in the art, but the '497 patent itself concedes that the transformation techniques used to put those components into fertile transgenic corn were known in the art. . . . The '497 patent even references the '798 patent, stating that "[m]ethods for production of glyphosate resistant corn plants also have been described...(U.S. Pat. No. 5,554,798)." Exhibit B at 2:40-42. In other words, not only were all of the transgenic pieces of DNA used in GA21, FI117, GG25 and GJ11 in the prior art, but

the process for combining those pieces and inserting the resulting combination into corn to make fertile transgenic corn was known in the art.

(Doc. #624 at p. 6). DeKalb argues, nevertheless, that its contribution was novel and patentable because its scientists transformed the corn and, thereby, “located” RPA’s plasmid in the transformation event, which “location” was novel. DeKalb’s argument proves the opposite. Neither RPA nor DeKalb “selected” the insertion site, which was totally random. (DeRose Tr. 218-20). The invention of the claim 46 comprised a specific DNA plasmid in a fixed position in the chromosome. The unique and non-obvious insertion of the DNA constructs into the corn was a joint contribution of RPA’s and DeKalb’s scientists. Absent RPA’s submission of the DNA specifically for those transformations, there would have been no transformation events. Thus, if RPA’s contribution were irrelevant merely because their DNA constructs and their use in corn were “prior art” as of April 1997, the same would apply to DeKalb’s contribution, because DeKalb’s work was also “prior art.” The Court can no more discount RPA’s contribution because it was “prior art” at the time of filing of the patent application, than it can discount DeKalb’s contribution of its “prior art” transformation, regeneration and breeding steps.⁷

c. RPA’s 1997 PCT Application Is Not “Prior Art”

⁷ DeKalb relies heavily on an unreported and uncitable opinion of the Federal Circuit in *Clark v. B.H. Holland Co.*, Nos. 95-1008, -1020, -1441, 1996 U.S. App. LEXIS 11262 (Fed. Cir. May 14, 1996). Even if the case could be considered as precedent, it does not help DeKalb. In that case, the named inventor and asserted putative co-inventor had collaborated on an improvement to a barbecue grill years before the invention of the patent in suit. That initial improvement was on-sale for many years and was therefore clear prior art as of the time of the second invention which was the subject matter of the patent in suit. The asserted putative co-inventor had not collaborated at all on the second improvement. The case has no bearing where an invention is made during a collaboration and the contribution is confidential proprietary material of the contributor. The Federal Circuit did not suggest any principle that prior art status of a contribution as of the date of application for a patent is at all relevant, if the contribution was made during a collaboration and was then secret.

Even were the Court free to consider post-contribution and post-reduction-to-practice publications, RPA's 1997 PCT Publication was not "prior art" as of the April 3, 1997 filing date of the 497 patent, as a matter of law. First, it is not prior art under 35 U.S.C. § 102(a) because the publication is not "before the invention thereof by the applicant for patent." Second, it is not prior art under 35 U.S.C. § 102(b) because the 1997 PCT Publication's date is less than one year before the application date for the 497 patent. DeKalb has not explained how this publication can be "prior art" against RPA.

d. DeKalb's 1995 PCT Application is Irrelevant

Again, even were the Court free to consider post-contribution and post-reduction-to-practice publications, DeKalb's proffer fails to explain how anything in the 1995 PCT application discloses RPA's DNA constructs used in the four transformation events of the 497 patent. The publication is utterly irrelevant, even if it could be considered for determining joint inventorship.

V. JOINT INVENTORSHIP OF THE LUNDQUIST 798 PATENT

RPA notes that before trial the Court had raised the issue of RPA's standing to proceed with respect to the 798 patent. RPA's memorandum in support of its standing argument is attached as Appendix A to this brief.

A. Interpretation of Claim 1 of the 798 Patent

Claim 1 of the 798 patent may be diagramed as follows:

- A. A fertile transgenic *Zea mays* plant
- B. (i) containing an isolated heterologous DNA construct encoding EPSP synthase wherein said DNA construct is expressed
(ii) so that the plant exhibits resistance to normally toxic levels of glyphosate, wherein said resistance is not present in a *Zea mays* plant not containing said DNA construct, and wherein said DNA construct

- C. is transmitted through a complete normal sexual cycle of the transgenic plant to the progeny generation.

The parties stipulated to the proper interpretation of claim 1 of the 798 patent, except for the meaning of the phrase “so that the plant exhibits resistance to normally toxic levels of glyphosate, wherein said resistance is not present in a *Zea mays* plant not containing said DNA construct.” The Court construed the limitation for the advisory jury in an overly liberal fashion in DeKalb's favor to mean that “When the transgenic plant is exposed to any amount of glyphosate herbicide that would harm an otherwise comparable nontransgenic corn plant, the transgenic plant will not be adversely effected due to the presence of the EPSPS enzyme.”

In view of the evidence presented and the arguments of the parties during trial, however, the construction of the claim has no bearing on the determination of inventorship in this case, because even if the Court uses DeKalb's exact proffered construction, RPA's scientists are joint-inventors.

B. Lundquist and Walters Did Not Conceive Claim 1

1. Definition of Conception

“Conception” has a specialized meaning in patent law. As recently reaffirmed by the Federal Circuit in *Singh v. Brake*, No. 99-1259, ___ F. 3d ___, 2000 U.S. App. LEXIS 18745 (Fed. Cir. Aug. 4, 2000):

Conception is “the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice.” A conception must encompass all limitations of the claimed invention, and “is complete only when the idea is so clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.”

Id. at *11-12 (citations omitted).

In *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993), the Federal Circuit held:

Conception is a question of law that we review de novo. Although *Amgen* was the first case in which we discussed conception of a DNA sequence coding for a specific protein, we were not writing on a clean slate. We stated:

Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed chemical structure of the gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.

927 F.2d at 1206, 18 USPQ2d at 1021. We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility.

984 F.2d at 1168-69.

A mere idea of a general goal does not constitute conception of a claimed invention. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1575 (Fed. Cir. 1996) ("To be a joint inventor, one must contribute to the conception of an invention. Conception exists when a definite and permanent idea of an operative invention, including every feature of the subject matter sought to be patented, is known. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue") (citations omitted); *In re Deuel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995) ("knowledge of a protein does not give one a conception of a particular DNA encoding it").⁸

⁸ See also *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376, (Fed. Cir. 1986), (continued...)

2. No Conception by Lundquist or Walters

It may be conceded, *arguendo*, that Lundquist and/or Walters discovered parts A and C of claim 1 — i.e., a technique for making fertile transgenic corn in which some DNA construct is transmitted or heritable through normal sexual cycle to a progeny generation. That is not the claim that the PTO issued here. To the contrary, as much as DeKalb wishes to ignore it, claim 1 includes elements B(i) and B(ii), and DeKalb has not presented any evidence that Lundquist or Walters ever actually conceived of that subject matter.

Neither named inventor had ever worked with any EPSPS gene or any other glyphosate resistant genetic material prior to their patent applications. Walters testified:

Q: At the time that this patent application was filed in April 1990, what work had you personally done with any gene encoding EPSPS or any other gene that provides for glyphosate tolerance in corn?

A None that I recall.

Q None whatsoever?

⁸(...continued)

cert. denied, 480 U.S. 947 (1987) ("Conception is the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice."); *Burroughs Wellcome Co. v. Barr Lab., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994), *cert. denied*, 515 U.S. 1130 (1995) (An idea is sufficiently "definite and permanent" when "only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation. . . . Conception is the formation 'in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is therefore to be applied in practice.' Conception must include every feature or limitation of the claimed invention.") (citations omitted); *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998) ("Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice."); *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856 (1991) ("Conception is the 'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice. Conception requires both the idea of the invention's structure and possession of an operative method of making it.'") (citations omitted).

A No.

(Walters Tr. 760). Lundquist testified:

Q. And have you ever attempted to transform any plant in order to impart glyphosate resistance to that plant?

A. No, I have not.

Q. Have you ever worked with any plant which was purported to have glyphosate resistance of any sort?

A. You mean during my research career?

Q. During your research career, yes.

A. I don't recall working with any plants that were purported to have EPSP synthase.

(Lundquist Tr. 758). Further, neither Lundquist nor Walters ever envisioned any DNA constructs encoding EPSPS genes. Lundquist testified:

Q. Do you recall if you and David Walters mentioned any specific construct to encode the EPSPS synthase?

A. I don't remember whether we envisioned any specific construct, that is, you know, whether we had a conversation about this promoter and that piece of DNA and that EPSPS synthase, I don't remember.

Q. Sitting here today, is it fair to say that you do not recall that either you or David Walters had a specific construct in mind as to encode EPSPS or EPSP synthase?

A. I don't recall whether we had a specific construct in mind or not.

(Lundquist Tr. 759). Walters testified:

Q. What genetic constructs did you envision as of April 1990 that will provide glyphosate tolerance in transformed corn?

A. Generally, expression of aroA.

Q. AroA is a gene, correct?

A. It is.

Q. I think the question was, what genetic constructs did you envision as of April of 1990

A. I don't recall envisioning any specific construct, but generally constitutive expression of *aroA*.

(Walters Tr. at 763).

DeKalb, nevertheless, asserts that the text of Lundquist's January and April 1990 patent applications corroborates Lundquist's alleged conception and constructive reduction to practice of claim 1 of the 798 patent.⁹ RPA also relies on the same patent applications to prove the absence of the requisite conception or constructive reduction to practice. Thus, determining whether the April 1990 application (the second more complete continuation-in-part application) demonstrates conception of claim 1 necessarily determines whether Lundquist conceived of claim 1.¹⁰

The established body of patent law underlying the "written description" requirement of 35 U.S.C. § 112 is useful by analogy in determining Lundquist's application demonstrates conception. Further, "constructive reduction to practice" is directly a function of the written description requirement. *See Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 411 (1999):

⁹ For ease, the term "Lundquist" designates the purported inventive entity of Lundquist and Walters, unless otherwise indicated or required.

¹⁰ *Cf. Burroughs Wellcome Co.*, 40 F.3d at 1230 ("The Burroughs Wellcome inventors claim conception of these inventions prior to the NIH experiments, based on the draft British patent application. That document is not itself a conception, for conception occurs in the inventors' minds, not on paper. The draft simply corroborates the claim that they had formulated a definite and permanent idea of the inventions by the time it was prepared.").

For an earlier-filed application to serve as constructive reduction to practice of the subject matter of an interference count, the applicant must describe the subject matter of the count in terms that establish that he was in possession of the later-claimed invention, including all of the elements and limitations presented in the count, at the time of the earlier filing.

Therefore, it is appropriate to utilize the law of written description as developed in context of 35 U.S.C. § 112 in this case, not as a matter of validity of claim 1, but to determine whether Lundquist's April 1990 patent application demonstrates conception and constructive reduction to practice of claim 1 of the 798 patent.

The key written descriptions of the April 1990 patent application relating to these contentions are discussed below.

"Bacterial EPSPS synthase": DeKalb first argues that the April 1990 application evidences Lundquist conception of claim 1 by disclosing a technique for transforming corn that could be applicable to any DNA construct, and recited a bacterial EPSP synthase as a specific example of DNA that could be introduced into corn following that disclosed technique. The application states:

Suitable heterologous DNA for use herein includes all DNA which provides for, or enhances, a beneficial feature of the resultant transgenic corn plant. ... For example, the DNA can encode a ... bacterial EPSP synthase for resistance to glyphosate herbicide....

(PTX-1807 at p. 83, emphasis added). DeKalb also argues that Lundquist's original proposed claim 1 demonstrates that Lundquist conceived of transformed corn using any DNA. However, such a general assertion does not describe any DNA construct, much less a DNA construct for glyphosate resistance. The only claim that mentioned EPSPS specifically was expressly limited to only a "bacterial" EPSPS, as shown in proposed claim 7:

[A fertile transgenic Zea mays plant containing heterologous DNA which is heritable] wherein said heterologous DNA comprises a DNA sequence selected from the group consisting of a ... **bacterial EPSPS** (*sic*) synthase gene

(PTX-1807 at p. 117, emphasis added).

The above are the sole disclosures in the April 1990 application relating to EPSPS genes to provide glyphosate resistance in corn. (DeRose Tr. 246-47, 249). They demonstrate that Lundquist did not conceive or constructively reduced to practice the subject matter of claim 1 of the 798 patent.

First, "bacterial EPSPS" refers to *aroA* genes, but not necessarily mutated *aroA* genes. Indeed, Lundquist does not mention mutation of genes at all. (DeRose Tr. 255). Therefore, it is not apparent that Lundquist even thought about, much less conceived, of mutated bacterial EPSPS genes, or any mutated EPSPS genes. (DeRose Tr. 246-47).

Second, Lundquist does not mention any non-bacterial EPSPS genes, whether mutated or non-mutated, which, in the absence of any other information, demonstrates unequivocally that Lundquist had not even thought about, much less conceived of any such non bacterial EPSPS genes. (DeRose Tr. 255-56). Indeed, DeKalb's expert conceded:

Q. What in the patent application filed in April of 1990, discloses a mutated plant EPSPS gene that actually provides glyphosate resistance in corn?

A. There are none.

Q. And what information do you have that the petunia gene that you mentioned in the Weising article or wherever else that was available as of April 1990, ever provided glyphosate resistance in corn?

A. To my knowledge, I don't believe the petunia gene was used prior to that time for glyphosate resistance in corn.

Q. And since that time, has never been shown to provide glyphosate resistance in corn, correct?

A. I'm not absolutely sure of that.

(Quatrano Tr. 1035).

Third, Lundquist does not describe any DNA constructs containing any EPSPS genes, which, in this case, proves that Lundquist had not thought about, much less conceived of any DNA constructs for expressing EPSPS genes. (DeRose Tr. 250). Indicative of Lundquist's failure of conception and constructive reduction of practice is the failure to recognize the existence or importance of the transit peptide in imparting glyphosate tolerance. (DeRose Tr. 255, 302).¹¹

Dr. DeRose also testified:

Q. Now in your opinion, does the April 1990 patent application reasonable convey to the person of ordinary skill in the art of plant biotechnology, a description of a DNA construct for encoding an EPSPS or EPSP synthase for glyphosate resistance in corn? * * *

THE WITNESS: Okay. No. I wasn't able to find anything that directed me to how to build a DNA construct for EPSPS synthase.

(DeRose Tr. 256). This testimony was not challenged by any DeKalb witness, but was only reinforced by Dr. Quatrano, who testified that all elements of DNA constructs play a role in determining glyphosate resistance:

Q.. Is it correct, that DNA constructs make a difference as to whether you will get glyphosate resistance in a corn plant?

A. Yes. The construct does make a difference, but any construct that you put in would make a difference with respect to what kind of regulatory elements you have, whether you have a stop codon, whether -- if you wanted a target to a particular

¹¹ It may be that persons of ordinary skill in the art would have known years earlier that a transit peptide would be advantageous, if not required, although there was still debate in the literature as of 1990. (DeRose Tr. 302-08). But the issue is whether it had ever occurred to either Lundquist or Walters that there was such a thing as a transit peptide, or that it would be required to obtain glyphosate resistance in corn.

location, any of those regulatory elements would have to be in place so that the DNA construct in that particular instance would matter as to whether or not you got expression.

(Quatrano Tr. 1027-28). Lundquist's failure to describe DNA constructs of claim 1 proves lack of conception. Indeed, it is lack of conception of the single most critical element of claim 1, and one where there was no prior knowledge or success in the art.

In view of the above, established law of written description, relied on by analogy, requires a finding that Lundquist did not conceive of claim 1, as a matter of law. In *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993), the Federal Circuit analyzed the analogous written description issue as follows:

Revel argues that the disclosure of his Israeli application satisfies the written description requirement because it contains language of similar scope and wording to that of the [claim]. * * * Revel points to a claim in the original Israeli application that corresponds substantially to the language of the [claim]. According to Revel, since the language of the [claim] refers to a DNA and not to a specific sequence, the specification need not describe the sequence of the DNA in order to satisfy the written description requirement. Revel thus urges that only similar language in the specification or original claims is necessary to satisfy the written description requirement.

We disagree. Compliance with the written description requirement is a question of fact which we review for clear error. On reconsideration, the Board correctly set forth the legal standard for sufficiency of description: the specification of Revel's Israeli application must "reasonably convey to the artisan that the inventor had possession at that time of the . . . claimed subject matter."

An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. Revel's specification does not do that. Revel's application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain mRNA coding for B-IF. n11 A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA. Revel's argument that correspondence between the language of the count

and language in the specification is sufficient to satisfy the written description requirement is unpersuasive when none of that language particularly describes the DNA.*** To paraphrase the Board, one cannot describe what one has not conceived.*** Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived. (Citations Omitted)

984 F.2d at 1170-71.

Also important as an analogy is the Federal Circuit's decision in *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997), *cert. denied*, 118 S. Ct. 1548 (1998). University of California ("UC") obtained a patent relating to recombinant genetic materials that produce insulin in humans, mammals and "vertebrate animals." Eli Lilly asserted that the claims were invalid under the first paragraph of 35 U.S.C. § 112 for lack of written description, because UC's patent described only DNA sequence found in rats, but did not describe any human DNA, or DNA for mammals or "vertebrate animals" other than the rat. *Id.* at 1562. The district court held that, although the claims of the UC patent that provided an adequate written description of rat DNA, the claims were invalid under 35 U.S.C. § 112, paragraph 1, because the specification did not provide an adequate written description of the DNA required by the asserted claims. *Id.* at 1566. Affirming the district court's decision of invalidity, the Federal Circuit stated:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention."

An adequate written description of a DNA, such as cDNA of the recombinant plasmids and microorganisms of the '525 patent "requires a precise definition, such as by structure, formula, chemical name, or physical properties" not a mere wish or plan for obtaining the claimed chemical invention. . . . Accordingly, "an adequate

written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.”

Eli Lilly, 119 F.3d at 1566 (citations omitted).

The Federal Circuit then first considered claim 5, which is specific to DNA encoding human insulin. UC argued that a constructive or prophetic Example 6 in the UC patent specification described in sufficient detail how to prepare the claimed invention. The court rejected the argument, however, and held that did not provide a written description of the claimed invention:

Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. . . . Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Id. at 1567 (citations omitted).

The Court of Appeals also affirmed the district court's finding of invalidity of the claims directed to vertebrate or mammalian insulin, because the UC patent provided a written description of only DNA encoding the rat insulin. The Court held describing a rat insulin DNA was insufficient to support generic DNA claims, in language that is fully applicable here to DeKalb's argument that the reference to a bacterial EPSPS is a written description of claims directed to all “DNA constructs encoding EPSP synthase”:

Contrary to UC's argument, a description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA. A written description of an invention involving a chemical genus, like a description of a chemical species,

"requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials.

The cases UC cites in support of its argument do not lead to the result it seeks. These cases do not compel the conclusion that a description of a species always constitutes a description of a genus of which it is a part. These cases only establish that every species in a genus need not be described in order that a genus meet the written description requirement: ...

... In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, **a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA.** A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under § 112, ¶ 1, by showing the enablement of a representative number of species within the genus. ... We will not speculate in what other ways a broad genus of genetic material may be properly described, but it is clear to us, as it was to the district court, **that the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.**

Eli Lilly, 119 F.3d at 1568-69 (citations and footnote omitted; emphasis added).

In short, *Fiers* and *Eli Lilly* by analogy require a conclusion that the 1990 patent application does not corroborate conception of claim 1 or any "constructive reduction to practice." First, *Fiers* and *Eli Lilly* preclude an argument that claims directed to "DNA construct encoding EPSP synthase wherein said DNA construct is expressed" can be corroborated by a writing where no such DNA construct is described. As a matter of law, *Fiers* and *Eli Lilly* require that the "DNA constructs" here, to paraphrase the law, must be described by "sequence information indicating which nucleotides constitute [EPSPS] DNA." To paraphrase further, "a [DNA construct] is not defined or described by the mere name '[DNA construct]' even if accompanied by the name of the [EPSPS] protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the [DNA construct]." Nothing in the 1990 application describes any conception or "constructive reduction to practice" of any DNA construct, and certainly not any DNA nucleotide sequences that would encode a non-bacterial or mutated plant EPSPS enzyme.

Second, in *Eli Lilly* the Federal Circuit held that, although UC described DNA encoding rat insulin, that single description did not support generic claims directed to DNA encoding "human," "vertebrate," or "mammalian" insulin. By definition, a bare mention of bacterial EPSPS in the April 1990 application, without any DNA construct described at all, is insufficient to corroborate conception of any "DNA construct" encoding any EPSPS.¹²

¹² See also *Genentech Inc. v. Wellcome Found.*, 29 F.3d 1555, 1565 fn. 25 (Fed. Cir. 1994) ("The DNA isolate which is the subject of the '075 and '330 claims is itself defined in functional terms, i.e., as any sequence that encodes human t-PA. . . . [This] also give rise to a problem with the description requirement because the specification does not even remotely describe all the DNA sequences that encode the proteins within the scope of the functional definition.").

"Selectable Marker": DeKalb also argued the following "selectable marker" language in

Lundquist's 1990 patent applications:

The heterologous DNA to be introduced into the plant further will generally contain either a selectable marker or a reporter gene or both to facilitate identification and selection of transformed cells. Other selectable markers include . . . those genes which code for resistance or tolerance to glyphosate, 1,2-dichloropropionic acid methotrexate, imidazolinones, sulfonylureas, bromoxynil, phosphonothricin and the like. Those selectable marker genes which confer herbicide resistance or tolerance are also of commercial utility in the resulting transformed plants.

This language does not assist DeKalb, but further proves lack of conception and constructive reduction to practice. There were no selectable marker "genes which could code for resistance or tolerance to glyphosate" in corn as of April 1990. Indeed, even as of February 1994, DeKalb was never able to use DNA constructs encoding the bacterial EPSPS as a selectable marker in corn. (Spencer Tr. 1132-33; DeRose Tr. 202, 208, 248; PTX-240, 241, 179). Dr. DeRose testified without contradiction:

Q. And prior to DeKalb's report to you of this work with your DNA constructs being used for selection, to your knowledge, had anyone been able to select transformed corn with glyphosate?

A. Not to my knowledge, no, sir.

* * *

Q. Have any bacterial or EPSP synthase gene that were known as of April 1990, ever been tested to determine if they can act as selectable markers in corn?

A. Yes, there had. DeKalb had tested the CT7 gene and found they could not get it to work.

Q. Are you aware of anyone that has ever been able to obtain selection or to use as a selectable marker, any bacterial EPSPS gene that was known prior to April 1990?

A. No, sir. I'm not aware of anyone who has ever gotten a bacterial EPSPS gene, mutated or not mutated that was known before 1990, to work as a selectable marker.

Q. Are you aware as of April 1990, of there being any gene that was known to or available in the literature, patents or anywhere else, that coded for resistance or tolerance to glyphosate as a selectable marker in corn?

A. I'm not aware of any gene that had been used in corn as a selectable marker for glyphosate, no, sir.

(DeRose Tr. 202, 248-49).

DeKalb's Dr. Quatrano confirmed Dr. DeRose:

Q. What DNA construct or heterologous DNA does this application disclose that will provide a selectable marker that will be resistant to glyphosate, that is that you could use glyphosate as a selected agent?

A. This particular patent, 798 patent, does not disclose specific one. . . .

Q. Now again, are you aware of any DNA sequence, heterologous DNA, DNA construct, whatever, that was available as of April 1990, that in fact has been demonstrated to act as a selectable marker gene for glyphosate in corn?

A. In corn, okay. Since the transformation of corn didn't occur until then, I know of no specific example in transforming maize.

(Quatrano Tr. 1029). Mr. Spencer confirmed that DeKalb tried to use the AroA genes as selectable markers, but failed. (Spencer Tr. 1132-34; PTX-240, 241).

Thus, Lundquist's 1990 patent applications do not describe or disclose any DNA construct or process for producing fertile transgenic corn comprising DNA selectable marker gene where the DNA is expressed so as to impart glyphosate resistance to the corn. Lundquist's references to selectable markers in the 1990 patent applications demonstrates only the lack of conception and lack of constructive reduction to practice of selectable markers for glyphosate selection, and, thus, do not aid in establishing conception of claim 1 of the 798 patent.

Alleged State of the Art: DeKalb argues that Lundquist conceived claim 1 if persons skilled in the art would have been enabled to derive the full scope of claim 1 from the 1990 application's

description of a transformation technique and statement that any DNA construct could be used in that technique.

The argument is factually without support, because there is no evidence that any persons were so enabled, particularly given the undisputed evidence of the difficulty of deriving DNA constructs for glyphosate resistance in corn, and the failure of others to succeed, as DeKalb's own experts, Drs. Armstrong and Padgett, admitted. For DeKalb's argument to be factually well-founded, at a minimum, DNA constructs for glyphosate resistance in corn would have had to be known in the art before April 1990, so that those DNA constructs could be incorporated into Lundquist's disclosed technique. DeKalb's own expert scuttled the factual basis for that theory by admitting that no DNA constructs known in the art as of April 1990 are capable of glyphosate resistance in corn:

Q. . . . Can you identify for the jury any DNA construct that was disclosed in the literature, in patents, wherever else publicly available prior to April of 1990, which DNA construct was eventually shown to provide glyphosate resistance in corn?

A. I don't believe that I can point to that evidence.

(Quatrano Tr. 1025).

More importantly, the argument is legally incorrect. The issue is whether *Lundquist* conceived claim 1, not whether they enabled others to conceive. *Burroughs Wellcome Co.*, 40 F.3d at 1232 ("For conception, we look not to whether one skilled in the art could have thought of the invention, but whether the alleged inventors actually had in their minds the required definite and permanent idea."). No authority supports the conclusion that conception of a claimed invention can be demonstrated by showing that the alleged inventor enabled others to make the invention, if that inventor did not conceive or was able to describe the claimed invention. *Cf. Lockwood v. American*

Airlines, Inc., 107 F.3d 1565, 1571-72 (1997), discussing a patentee's right to rely on a prior application for priority:

The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. ... Lockwood argues that all that is necessary to satisfy the description requirement is to show that one is "in possession" of the invention. Lockwood accurately states the test, but fails to state how it is satisfied. One shows that one is "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. ... One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. Although the exact terms need not be used *in haec verba*, ... the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.

107 F.3d at 1571 (citations omitted).

In short, Lundquist's 1990 patent applications demonstrates the lack of its conception and constructive reduction to practice of claim 1.

C. RPA Scientists Significantly Contributed to the Conception of Claim 1 of the 798 Patent

RPA's claim of co-inventorship of the 798 patent is straightforward. Preliminarily, claim 1, by its plain language, is directed to "DNA construct encoding EPSP synthase wherein said DNA construct is expressed" to provide glyphosate resistant corn. The parties agree that claim 1 encompasses DNA constructs comprising any plant-derived or other non-bacterial mutated EPSPS gene, including DNA constructs with RPA's 2xmzEPSPS. (Hearing, August 11, 2000 Tr. 9-12).

Prior to RPA's involvement, neither Lundquist or anyone else at DeKalb had "form[ed] . . . a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." At most, Lundquist or others at DeKalb may have had some hope that someone

would develop a DNA construct for glyphosate resistance in corn, but they did not have an “the idea [that] is so clearly defined in the inventor’s mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.”

Elements B(i) and B(ii) of claim 1 were conceived by RPA’s inventors, who submitted to DeKalb for corn transformation and testing DNA constructs comprising maize EPSPS genes that were manifestly complete, definite and operative. Thereafter, DeKalb reduced claim 1 to practice when Michael Spencer introduced RPA’s DNA constructs into corn and successfully tested the resulting plants.

Thereafter, DeKalb recognized the success of RPA’s conception and contribution of plant-derived mutated EPSPS genes and DNA constructs containing them by amending its proposed patent claims to now encompass RPA’s conceptions and contributions.

Simply stated, but for RPA’s contribution, there is no evidence on the basis of which DeKalb did, or could have, conceived the full scope of claim 1 of the 798 patent. Only RPA provided the basis for the full scope of claim 1 — i.e., that encompasses a fertile transgenic *Zea mays* plant containing an isolated heterologous DNA construct encoding non-bacterial or plant-derived EPSP synthase wherein said DNA construct is expressed so that the plant exhibits resistance to normally toxic levels of glyphosate. RPA is entitled to joint inventorship with respect to the full scope of claim 1 because it contributed to DeKalb the conception of non-bacterial plant-derived EPSPS genes within the scope of claim 1.

Further, RPA was the first to conceive DNA constructs for glyphosate resistance in corn. There is insufficient, if any, evidence that anyone prior to RPA’s contribution in fact described or disclosed DNA constructs for glyphosate resistance in corn, or in fact obtained glyphosate resistance

in corn, no matter how claim 1 is construed. That conclusion becomes even more inescapable when the limitation "resistance to normally toxic levels of glyphosate" is properly construed to mean that the transgenic corn is not adversely affected by normal application of glyphosate due to the EPSPS gene, while an otherwise comparable control plant is harmed. DeKalb did not even attempt to make a record of anyone having had conception of claim 1 as so construed before RPA's contribution.

The prosecution history of the 798 patent supports RPA's contribution to claim 1. It was also only after RPA submitted to DeKalb its non-bacterial DNA constructs (*e.g.*, the 2xmzEPSPS DNA constructs) and DeKalb started to work with them that DeKalb envisioned broadening the pending patent claims to encompass the breadth of the current claim 1. Indeed, it was only at that point that DeKalb could have conceived the full scope of the current claims, because RPA's genes supplied "a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice" of such non-bacterial EPSPS or a mutated plant EPSPS genes.

Claim 1 of the 798 patent did not exist when Lundquist filed the 1990 patent applications. The claim was added after RPA had collaborated with DeKalb. (*See generally* Fiorito Tr. 775-85; JTX-2; PTX-1807). DeKalb first introduced claims encompassing RPA's DNA constructs in August 1993, shortly after DeKalb obtained the first successful results with RPA's DNA constructs. (*Id.*; PTX-179; DeRose Tr. 173-76) A claim resembling claim 1 first appeared in the prosecution history in August of 1995. (Fiorito Tr. 781).

Further confirming the contribution of RPA's scientists to the conception of claim 1, it is noted that the 798 patent issued only after DeKalb submitted the so-called Spencer Declaration to the PTO. That Spencer Declaration contained two examples, with example 2 being directed to tests of corn callus transformed with RPA's 2xmzEPSPS gene. (DeRose Tr. 256-59; PTX-1807 at 807).

Example 1 related to Calgene's bacterial *aroA* gene (using a complex construct including a bar gene as a selectable marker) (DeRose Tr. 259-60, 333; PTX-1807 at 807), and, thus, by itself would not have provided any evidence of non-bacterial EPSPS genes.

In sum, RPA scientists significantly contributed to the conception of the full scope of claim 1 of the patent.

**D. RPA Proved by Clear and Convincing Evidence
Joint Contribution to Claim 1**

Collaboration or "working jointly" does not mean that the inventors had directly worked with each other. Section 116 provides that persons may be joint inventors even if "(1) they did not physically work together or at the same time, [and] (2) each did not make the same type or amount of contribution. . . ." In *Kimberly-Clark Corp. v. Proctor & Gamble Distributing Co.*, 973 F.2d 911 (Fed. Cir. 1992), the Federal Circuit explained the statutory requirement as follows:

For persons to be joint inventors under Section 116, there must be some element of joint behavior, such as collaboration *or working under common direction*, one inventor seeing a relevant report and building upon it or hearing another's suggestion at a meeting. ...

... We therefore hold that joint inventorship under Section 116 requires at least some quantum of collaboration or connection.

973 F.2d at 917 (emphasis added).

There is plainly a sufficient quantum of collaboration or connection between the named and the RPA inventors, working through DeKalb. First, Lundquist transformed corn (whether or not the first to do so), which technology DeKalb acquired by 1992. (Spencer Tr. 1048-50):

Knowing of DeKalb's corn transforming capability, RPA's inventors gave DeKalb the necessary elements to make the glyphosate resistant corn invention. (DeRose Tr. 101-02). RPA's

inventors conceived at least of the non-bacterial mutated plant EPSPS genes that are a necessary part of the full scope of the 798 patent claims, and which were never conceived by Lundquist. They also provided DNA constructs that provided for a "plant [that] exhibits resistance to normally toxic levels of glyphosate, wherein said resistance is not present in a *Zea mays* plant not containing said DNA construct," which DeKalb did not have at all, and certainly not with a DNA construct encoding a non-bacterial mutated EPSPS gene.

DeKalb's personnel put together the two prongs of the invention — corn transformation and the EPSPS DNA constructs for glyphosate resistance — and that is the necessary "quantum of collaboration or connection" under DeKalb's "common direction" to allow joint inventorship.

E. RPA's Contributions Were Not Well Known or Current State of the Art

With respect to DeKalb's arguments based on Dr. Luca Comai's alleged contribution and the 1988 Monsanto patent application, RPA incorporates its prior discussion in Section IV. C., *supra*.

VI. SPECIFIC RPA INVENTORS - 798 AND 497 PATENTS

The jury specifically concluded that five RPA scientists should be named as co-inventors on both the 798 and 497 patents. That finding is well-supported and should be followed by the Court.

Three of the co-inventors — Drs. DeRose, Freyssinet and Lebrun — testified at trial about what they did and contributed, and also what the other two co-inventors — Drs. Leroux and Sailland — contributed. They testified that the five worked as a team with respect to the relevant endeavors relating to glyphosate resistant corn. Dr. DeRose testified that the contributors to RD-125 were "a team of people, including myself. The people that were involved were Michel Lebrun, Georges Freyssinet, Bernard Leroux, Alain Sailland." (DeRose Tr. 461-62; *see also* Freyssinet Tr. 640-41,

661-63, 665; Lebrun Tr. 515-16). Some of the contributions of the individual scientists, to the extent they can be extracted from the team research effort, are summarized as follows:

- Rick DeRose: Originated RD-125, including "clean" OTP (DeRose Tr. 223-26); invented the combination of elements of the DNA construct in GG25 (*Id.*); originated the methionine between the OTP and the 2xmzEPSPS (DeRose Tr. 222); advised DeKalb to use the rice actin promoter (DeRose Tr. 239); contributed to the design and construction of the maize histone promoter (Freyssinet Tr. 662); created the OTP-EPSPS junction (Freyssinet Tr. 662).
- Georges Freyssinet: Directed the team that performed much of the glyphosate tolerance work (DeRose Tr. 102; Lebrun Tr. 515, 530-31); suggested to DeKalb the use of the rice actin promoter (Freyssinet Tr. 632-33); co-conceived, and provided DeKalb, in June 1991, a construct drawing that included the rice actin promoter, OTP, and on EPSPS gene (Freyssinet 633; DTX-290); contributed to the development of the rice actin and histone promoters (Freyssinet Tr. 663); contributed to the development of the concept corn line that was used to isolate the maize gene for the mutant maize EPSPS gene (Freyssinet Tr. 663); co-originated the idea to combine the mutations in the 2mzmEPSPS (Lebrun Tr. 547-48).
- Michel Lebrun: Isolated materials to construct the OTP, constructed the OTP, co-invented the OTP, and conducted experiments regarding its effectiveness (Lebrun Tr. 510-16); tested promoters, including the histone promoters, for effectiveness (Lebrun Tr. 518-19); co-developed the 2mzmEPSPS (Lebrun Tr. 522-30); isolated maize DNA for use in mutated maize genes (Freyssinet Tr. 626); co-conceived the rice actin/OTP/EPSPS construct (Freyssinet Tr. 633).
- Bernard Leroux: Key inventor of the OTP (Lebrun Tr. 515-16, 565); co-originated the idea to use OTP in association with the EPSPS gene (DeRose Tr. 224); co-invented

the maize histone promoter (Freyssinet Tr. 655); co-originated the idea to use the maize histone promoter in association with the EPSPS gene (DeRose Tr. 221-22); co-originated the idea to use the hybrid histone promoter with the EPSPS gene (DeRose Tr. 225-26).

- Alain Sailland: Co-invented the OTP (Lebrun Tr. 516, Freyssinet Tr. 641); contributed to the development of the OTP by performing "most of the work dealing with the analysis of protein released inside the chloroplast" (Lebrun Tr. 516); co-conceived the idea to use the OTP in association with the EPSPS gene (DeRose Tr. 222); worked with Transgene to create the 2mzmEPSPS (Lebrun Tr. 549, Freyssinet Tr. 627); performed the enzymatic analysis of the 2mzmEPSPS (Freyssinet Tr. 691).

VII. RESPONSE TO DEKALB'S "PROFFER OF EXCLUDED EVIDENCE"

On August 31, 2000, DeKalb filed DeKalb's Proffer of Excluded Evidence citing three points of evidence that DeKalb asserts the Court improperly excluded from trial. (Doc. # 658) The issues with respect to the 1995 and 1997 PCT Patent Applications have been already addressed. (Section IV.C.3., *supra*). The following is RPA's response to the remaining points raised by DeKalb.

A. The 1991-1993 Correspondence

RPA's disagrees with DeKalb's fundamental characterization that the 1991-1993 correspondence was "excluded." It was not "excluded." DeKalb was allowed by the Court to present the 1991-1993 correspondence if it related to any proper issue underlying RPA's joint-inventorship claims, including any issue raised by the jury verdict form (Hearing 8/21/00 Tr. 33; 8/30/00 Tr. 1249-50). The Court only excluded irrelevant and confusing arguments to the jury.

DeKalb alleges that the evidence is relevant because it supposedly reflects (1) the alleged "understanding" of those skilled in the art "that supplying genes and promoters may not be a

significant contribution to the creation of fertile transgenic corn plants containing those genes and promoters, and (2) the purported co-inventors knowledge and silence that DeKalb was filing patent applications on corn with the genes supplied by RPA.” (Doc. #658 at pp. 1-2).

DeKalb does not demonstrate any relevance of the evidence. First, the 1991 or 1993 discussions did not involve inventorship of the particular claims here in issue, and DeKalb does not argue to the contrary.

Second, even were there a factual basis for considering that these discussions related to the naming of inventors of the two claims in issue, what “people of skill in the art” understood about the naming of inventors is legally irrelevant. Legal conclusions of even highly skilled technical people do not assist in the application of the legal principles to the facts here.

Inventorship is prescribed by the Patent Code, 35 U.S.C. §§ 102(f), 111(a)(1), 116 and 256. Nowhere do those statutes allow consideration of “common wisdom” or “understanding of one of ordinary skill” at all, much less permit such understandings to replace or supplement the statutory dictates. *See Gayler v. Wilder*, 51 U.S. 477, 494 (1850) (as patent law is statutory in nature, “no rights can be acquired in [a patent] unless authorized by statute, and in the manner the statute prescribes”).

B. RPA’s Naming of Inventors on its Patent Applications

RPA’s practices in naming inventors on its own patents is irrelevant. DeKalb asserts that the alleged practice shows that “those of skill in the art understood that supplying genetic material on a patent that claims plants derived from the supplied genetic material - even when the genetic material was supplied as part of a collaboration.” (Doc. # 658 p. 4). DeKalb’s argument fails.

First, as noted above, inventorship is prescribed by the Patent Code, 35 U.S.C. §§ 102(f), 111(a)(1), 116 and 256. Nowhere do those statutes allow parties to ignore or circumvent the Patent Code requirement that patents be issued in the name of the true inventors by alleged “admissions” or other practices. Nor do the statutes require any element of intent or equity in determining inventorship, except in cases of “deceptive intent” (applicable only when named inventors move to amend inventorship), which is not here in issue. *See Gayler v. Wilder*, 51 U.S. 477, 494 (1850) (as patent law is statutory in nature, “no rights can be acquired in [a patent] unless authorized by statute, and in the manner the statute prescribes”).

Second, RPA’s alleged past naming of inventors on *entirely different* patents with *entirely different* claims has no relevance to whether RPA’s inventors should be named inventors on the specific patents here in suit. Even assuming RPA has omitted proper inventors from its own patent applications (which it has not), this “wrong” does not make DeKalb’s actions “right.” No authority even remotely suggests that such evidence is relevant.

Third, if the evidence was relevant at all, its probative value would be substantially outweighed by waste of time and resources, and the confusion, that the evidence would contribute. DeKalb’s theory would force a “trial within a trial” involving individualized determinations of inventorship of the claims of each patent raised by DeKalb. This would have exponentially lengthened the trial, for a point that is irrelevant, or, at best, of extremely marginal probative value.

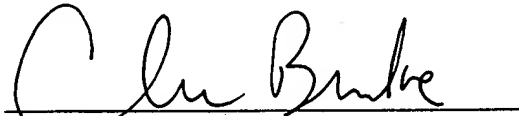
DeKalb specifically asserts that RPA’s failure to name Dr. DeRose on one of its French patents relating to the 2xmzEPSPS is significant in evaluating Dr. DeRose’s contribution because that patent “describes” RD-125. (Doc # 658 at p.5). DeKalb has not demonstrated any probative value of the evidence. There is simply nothing in the evidence or DeKalb’s proffer to suggest that

the French patent claims embodied any invention attributable to Dr. DeRose, or that French patent law on inventorship is sufficiently analogous to United States patent statutes such that failure to name Dr. DeRose on the French patent application had any bearing here. Also, DeKalb is incorrect in asserting that it was "precluded" from cross examining RPA about this patent. DeKalb did not even attempt to try to cross-examine Dr. DeRose on the French patent or argue that it was specifically relevant to any issue. Therefore, any argument DeKalb has about this patent is waived.

CONCLUSION

RPA respectfully requests that the Court issue an Order:

- A. Correcting, pursuant to 35 U.S.C. § 256, U.S. Patent 6,040,497 to include as co-inventors: Rick DeRose, Georges Freyssinet, Michel Lebrun, Bernard Leroux, and Alain Sailland
- B. Correcting, pursuant to 35 U.S.C. § 256, U.S. Patent 5,554,798 to include as co-inventors: Rick DeRose, Georges Freyssinet, Michel Lebrun, Bernard Leroux, and Alain Sailland



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Date: September 29, 2000

CERTIFICATE OF SERVICE

I hereby certify that on this day of September 29, 2000, a true and correct copy of the attached document was caused to be served on the attorneys of record at the addresses as indicated below by the methods of service indicated below:

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